

The Auditor-General  
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Performance Audit

# **The National Blood Authority's Management of the National Blood Supply**

Australian National Audit Office

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of Australia 2011

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Canberra ACT  
12 October 2011

Dear Mr President  
Dear Mr Speaker

The Australian National Audit Office has undertaken an independent performance audit in the National Blood Authority in accordance with the authority contained in the *Auditor-General Act 1997*. I present the report of this audit and the accompanying brochure to the Parliament. The report is titled *The National Blood Authority's Management of the National Blood Supply*.

Following its presentation and receipt, the report will be placed on the Australian National Audit Office's Homepage—<http://www.anao.gov.au>.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Ian McPhee'.

Ian McPhee  
Auditor-General

The Honourable the President of the Senate  
The Honourable the Speaker of the House of Representatives  
Parliament House  
Canberra ACT

## AUDITING FOR AUSTRALIA

The Auditor-General is head of the Australian National Audit Office (ANAO). The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits, financial statement audits and assurance reviews of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Australian Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

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# Abbreviations

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AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
AHPs	Approved Health Providers
ANAO	Australian National Audit Office
ARCBS	Australian Red Cross Blood Service, now known as the Blood Service
ARCS	Australian Red Cross Society, now known as the Red Cross
CTEPC	Clinical Technical and Ethical Principal Committee
Deed	The Deed of Agreement between the ARCS and the NBA
DoHA	Department of Health and Ageing
FMA Act	<i>Financial Management and Accountability Act 1997</i>
IVIg	Intravenous Immunoglobulin
JBC	Jurisdictional Blood Committee
KPI	Key Performance Indicator
Minister	Minister for Health and Ageing
MCA	Multi-Criteria Analysis
NBA	National Blood Authority
NBA Act	<i>National Blood Authority Act 2003</i>
NSPB	National Supply Plan and Budget
OBFM	Output Based Funding Model

ORBS	Ordering and Receipting Blood System. Now called BloodNet.
rFVIII	recombinant Factor V111
SIMDS	Sector Information Management and Data Strategy
TGA	Therapeutic Goods Administration



# Glossary

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Apheresis	A procedure in which blood is temporarily withdrawn, one or more components are selectively removed, and the remainder of the blood is reinfused into the donor.
Blood sector	The organisations (government and non-government), professionals and other employees or volunteers involved in the collection, production and provision of blood and blood products to the Australian community.
Blood products	Products manufactured from donated human blood.
Blood-related products	Products that are used or intended for use for human therapeutic or diagnostic purposes and that are alternative or complementary to the use of blood products, and are regarded as blood-related products for the National Blood Agreement.
Fractionation	The separation of blood plasma into its basic components.
Fresh blood components	Whole blood or components of whole blood such as red blood cells, platelets and plasma.
Haemophilia	Hereditary deficiency of clotting factors in blood.
Intravenous Immunoglobulin (IVIg)	IVIg is a blood product (derived from plasma) administered intravenously to treat immune deficiencies, inflammatory and autoimmune diseases, and acute infections.
Leucodepletion	Removal of white cells from a blood product.
National Blood Agreement	An agreement signed in 2003 by the Commonwealth, state and territory governments to implement a coordinated approach to policy setting, governance and management of the Australian blood sector.

Plasma	Liquid portion of blood that contains proteins.
Plasma-derived products	Blood products such as albumin, immunoglobulin and coagulation factors, which are isolated from blood plasma by various fractionation techniques.
Plasma-apheresis	Automated procedure for removing whole blood from the donor, separating out the plasma and returning the remaining components to the donor.
Platelets	One of the cellular components of blood that contribute to blood clotting.
Recombinant product	A synthetic or manufactured blood product, for example, recombinant Factor VIII used to treat haemophilia patients.

# Summary and Recommendations



# Summary

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## Australia's blood supply

1. A reliable supply of blood and blood products is an integral component of Australia's medical support system, critical in the treatment and support of people with a range of clinical conditions.<sup>1</sup> Recipients of blood and blood products include cancer patients, victims of traumatic accidents, people undergoing surgery, and those with blood disorders such as haemophilia, to state just a few.

2. Australia is fortunate in having a largely self-sufficient blood supply. By arrangements with Australian governments, the national supply of blood is primarily attained through a long-established system of voluntary, unpaid blood donations collected from individual donors by the *Australian Red Cross Blood Service* (ARCBS), a division of the not-for-profit *Australian Red Cross Society* (ARCS).<sup>2</sup> Blood products are provided free to patients requiring treatment, through Approved Health Providers (AHPs).

3. In 2009–10, around half a million Australians made some one million blood donations through ARCBS collection centres. These donations constitute Australia's fresh blood supply and are used to produce the majority of our blood products.<sup>3</sup> To meet growing demand in terms of quantity, high quality and state-of-the-art blood products, the blood supply is also supplemented with imported plasma-derived and recombinant (synthetic) blood products.

## Managing rising cost and demand

4. The administration and coordination of Australia's blood supply (including the collection, testing, processing and distribution of fresh blood and blood products) is funded under a joint arrangement between the Australian Government, which contributes 63 per cent of the total blood

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<sup>1</sup> Blood products are components derived from human blood, for example plasma, platelets and Immunoglobulins.

<sup>2</sup> Late in the audit, 'ARCS' and 'ARCBS' changed to the 'Red Cross' and the 'Blood Service' respectively. However, for simplicity, the use of ARCS and ARCBS have been retained throughout this report.

<sup>3</sup> Under Government contractual arrangements, the ARCBS is the single provider of plasma to CSL Limited for the manufacture of plasma-derived products for use in Australia.

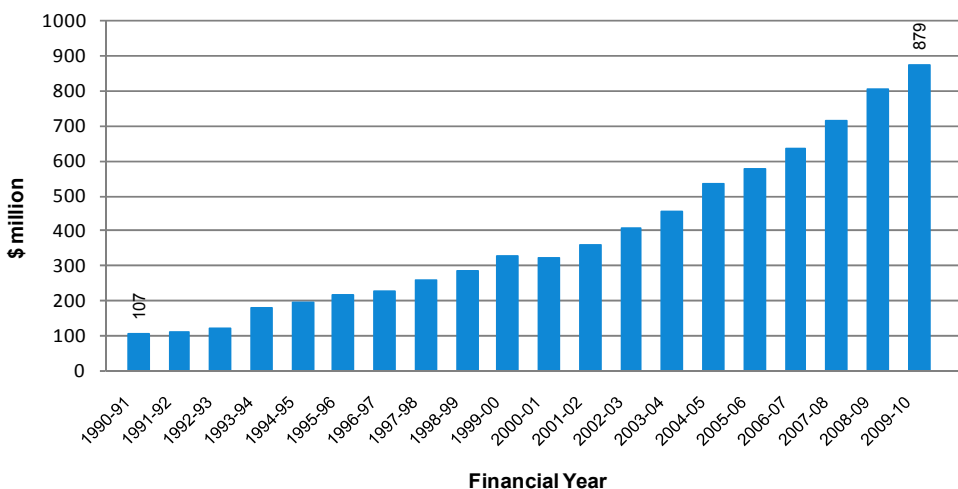
budget, and the states and territories, which collectively contribute 37 per cent of funding.

5. Over the last two decades, government expenditure for blood products and services has steadily risen (Figure 1). In part, this is attributed to higher demand for blood and blood products, resulting from the growth and ageing of Australia’s population and the increased use of blood products for new clinical treatments. The introduction of additional quality measures to ensure continuing blood product and service safety can also add to costs.

6. These factors contribute to pressure on governments and the blood sector (including AHPs and product and service providers) to manage Australia’s blood supply more efficiently, demonstrate value for money and measure progress against defined policy objectives, without compromising the quality and safety of the nation’s blood products and services.

**Figure 1**

**The cost of Australia’s blood and blood products 1990 to 2010**



Source: NBA, Department of Health and Ageing, and the Stephen Review 2001.

7. In responding to these challenges, a focus of Australian governments in recent years has been to strengthen national coordination of the blood sector, particularly by streamlining the purchasing of products to assure the affordability and reliability of supply. A major review of the blood banking and plasma sector in 2001 led to several recommendations for blood sector

reform, including the establishment of a central coordinating agency—subsequently founded as the National Blood Authority (NBA).<sup>4</sup>

8. This audit focuses on the NBA’s role in managing the nation’s blood supply, bearing in mind the NBA’s legislative responsibilities, national policy objectives and ongoing blood sector reforms.

## National coordination arrangement

### The National Blood Authority

9. The NBA was established in 2003 under the *National Blood Authority Act 2003* (NBA Act).<sup>5</sup> It is a statutory agency within the Health and Ageing portfolio, with an average staffing level of 47.<sup>6</sup>

10. Since its establishment, the NBA has been responsible for the planning and coordination of the national blood supply, including the centralised purchase of blood and blood services, on behalf of the Australian, state and territory governments. In 2010–11 the agency’s total estimated budget was \$1.2 billion.<sup>7</sup>

11. Under the Health and Ageing portfolio’s Outcomes and Programs structure, the NBA has one Outcome:

#### NBA Outcome

Access to a secure supply of safe and affordable blood products, including through national supply arrangements and coordination of best practice standards within agreed funding policies under the national blood arrangements.<sup>8</sup>

12. In pursuing this Outcome, the NBA is required to operate in accordance with:

- the NBA Act, which defines the NBA’s functions; and

<sup>4</sup> Sir Ninian Stephen, *Review of the Australian blood banking and plasma products sector*, 2001 (the Stephen Review).

<sup>5</sup> The NBA is an FMA Act agency and part of the Health and Ageing portfolio.

<sup>6</sup> *Health and Ageing Portfolio Budget Statement 2010–11*, p. 694.

<sup>7</sup> *ibid.*, p. 691. The NBA’s total estimated budget includes: ordinary annual services under Appropriation Bill (No. 1), consisting of Departmental Appropriation (\$5.61 million) and Administered resources for Outcome 1 (\$5.75 million); and \$1.217 billion total special account for blood services and products.

<sup>8</sup> National Blood Authority Australia, *Annual Report 2009–10*, p. 28; and *Health and Ageing Portfolio Budget Statements 2010–11*, p. 693.

- blood sector policy principles as conveyed through a National Blood Agreement<sup>9</sup>, an agreement endorsed by the Australian, state and territory governments.

13. Consistent with these requirements, as the national coordinating agency, the NBA defines its role as:

- coordinating national demand and supply planning of blood and blood products and purchase those products on behalf of all Australian governments;
- negotiating and manage contracts on behalf of all States and Territories and the Australian Government with suppliers of blood and blood products to enable the development of an agreed single national pricing schedule;
- implementing an efficient demand driven system, based upon evidence and good clinical practice, so that the blood supply system is highly responsive to needs; and
- working in a collaborative manner with all governments and other responsible parties to ensure that Australia's blood supply is adequate, safe, secure and affordable.

Source: NBA Corporate Plan 2006–09, p. 2.

## **Governance arrangements**

14. Governance of the NBA and the blood sector is multifaceted. The NBA itself is headed by a General Manager who is responsible for the day-to-day management of the NBA and reports to the Minister for Health and Ageing. As required by the NBA Act, the Minister has established a NBA Board, which functions as an advisory board to the General Manager. In addition to these arrangements, the NBA's operations are overseen by a Jurisdictional Blood Committee (the JBC) comprised of state, territory and Australian government representatives (Figure 2).<sup>10</sup>

15. The approval of major national blood policy and high-level oversight of the NBA and the blood sector are responsibilities of the Health Ministers, represented through the Australian Health Ministers' Conference (AHMC). The JBC reports to the AHMC through two sub-committees, the Australian Health Ministers' Advisory Council (AHMAC) and the Clinical, Technical and Ethical Principal Committee (CTEPC). The JBC is the NBA's main conduit for government endorsement of blood supply planning and budgets, policy development and referral of significant blood-related issues to AHMAC and AHMC.

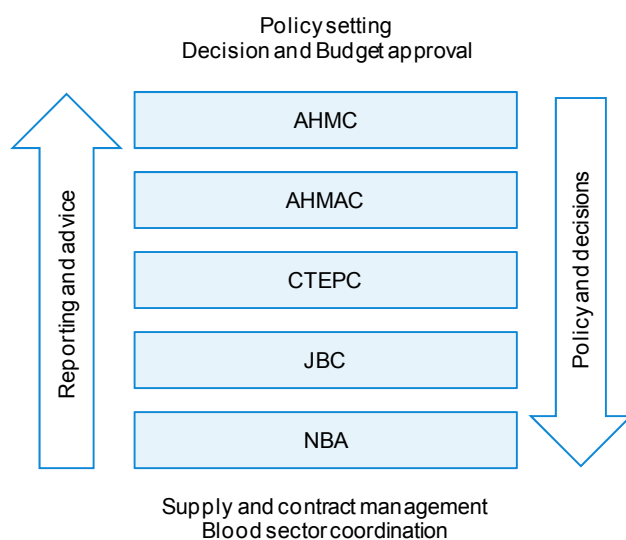
<sup>9</sup> National Blood Agreement 2002.

<sup>10</sup> The NBA also provides the secretariat for the JBC.



Figure 2

## Governance committee hierarchy



Source: ANAO.

Note: AHMC (Australian Health Ministers' Conference), AHMAC (Australian Health Ministers' Advisory Council), CTEPC (Clinical, Technical and Ethical Principal Committee), JBC (Jurisdictional Blood Committee), and NBA (National Blood Authority).

### Contractual arrangements for Australia's blood supply

16. To ensure a sufficient and affordable blood supply, a major function assigned to the NBA through its Act is the purchase of blood products and services on behalf of the Commonwealth, states and territories. As the central purchasing agency, the NBA establishes contracts with suitable providers to meet the needs of patients, within the resources and policy parameters set by Australian governments (Figure 3).

17. In 2009–10 the NBA had 14 contracts for the supply of blood or blood products, with expenditure totalling \$879 million.<sup>11</sup> Of this amount:

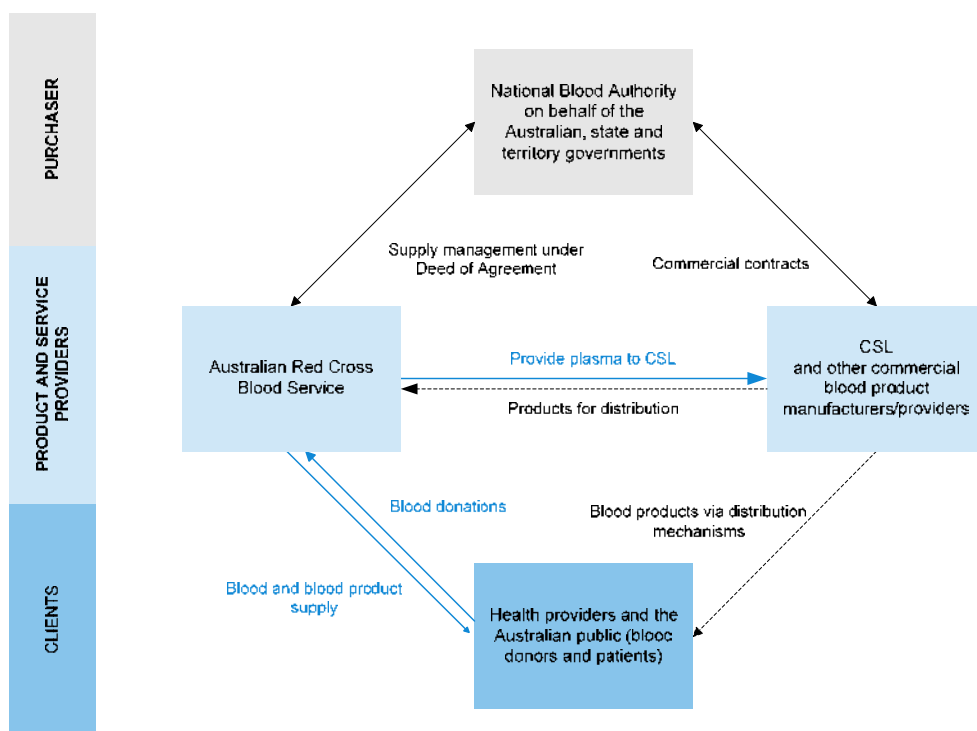
- \$456 million (around 50 per cent) was for the nationwide provision of fresh blood products and services by the ARCBS under a Deed of Agreement (the Deed); and

<sup>11</sup> op. cit. *NBA Annual Report 2009–10*, pp. 45, 57–58; and *Health and Ageing Portfolio Budget Statement 2010–11*, p.713.

- \$215 million provided imported plasma-derived and recombinant products, through several NBA–commercial provider contracts (a government contingency measure intended to supplement supply where demand for specific products exceeds domestic production capacity or where specialised products are required); and
- \$182 million was for the provision of fractionated products produced by CSL from domestic plasma.

**Figure 3**

**Purchaser–provider arrangements for the blood sector**



Source: ANAO.

**Audit objective and scope**

18. The audit objective was to assess whether the NBA’s governance and contractual arrangements are effective in securing a national supply of blood products and services. To achieve this, the ANAO examined the NBA’s performance against three high-level criteria, which focused on: governance and administrative systems to support the supply of blood products and services; contract management practices; and performance monitoring.

19. Particular attention was given to the NBA's management of the Deed of Agreement with the ARCS, a not-for-profit organisation and provider of fresh blood products and services (through the ARCBS) in Australia. Procurement activities were also examined through a contract with Baxter Healthcare Limited, a commercial provider of blood products. The audit included stakeholder consultation in three states.

20. Regulatory matters involving the Therapeutic Goods Administration (TGA), and contracts with CSL or other blood product providers were not included in the audit.

21. Consistent with the *Auditor-General Act 1997*, the ANAO provided the proposed report to the NBA and DoHA, and relevant extracts of the proposed report to the TGA, ARCBS and Baxter Healthcare Pty. Limited, giving them the opportunity to respond to the report within 28 days.

## Overall conclusion

22. In 2001, a review of the blood sector (the Stephen Review) identified inefficiencies in the sector, including a lack of coordination and national focus, and rising costs of blood products and services—which had tripled between 1991 and 2001.<sup>12</sup> The establishment of the National Blood Authority (NBA) in 2003 was part of government reforms to improve blood sector efficiency and ensure a safe, secure, adequate and affordable blood supply into the future.<sup>13</sup>

23. As the national coordination agency, the NBA is required to provide access to safe and affordable blood products through its management of the national supply arrangements. This includes the centralised purchasing of blood products and services, and development of national mechanisms to monitor and address Australia's increasing blood supply expenditure and trends in blood product use.

24. To this end, the NBA has established organisational structures, and processes, which largely allow the agency to carry out its governance responsibilities. Consistent with *the National Blood Authority Act 2003* and the National Blood Agreement<sup>14</sup>, the NBA has assumed a central role in the

<sup>12</sup> op. cit. The Stephen Review, 2001.

<sup>13</sup> National Blood Agreement, 2002; and *The role of the NBA*, NBA Board inaugural Chair Richard Smallwood, 2003 [downloaded from the NBA website 22 March 2011].

<sup>14</sup> The Australian, state and territory governments are signatories to a National Blood Agreement, which sets out national blood policy objectives and roles, including the governance arrangements for the NBA.

national coordination of the blood supply through annual supply planning activities and contracting to purchase blood products and services. The NBA has also advanced (to varying degrees) a range of activities to improve the efficiency and effectiveness of the blood sector. These include measures to establish much needed data systems, promote appropriate use of products and reviews of various aspects of blood sector business—in particular, an extensive administrative review of the Australian Red Cross Blood Service (ARCBS).

25. Through these governance and contractual arrangements, the NBA has been largely effective in securing the national supply of blood and blood products. However, the NBA is not well positioned to monitor or address the trend in rising blood supply costs. The agency's ability to assess the overall cost-effectiveness of the blood program was affected by insufficient national data and a lack of mechanisms to determine the uptake and impact of initiatives to improve the blood sector.

26. In keeping with the governments' policy directions, and in the interest of ensuring the sustainability and affordability of the blood supply in the longer term, the NBA should strengthen the following areas of planning and program management:

- *Strategic priorities:* better defining the NBA's strategic directions and longer-term priorities (including for cost-efficiency), and communicating these to key stakeholders, would assist the blood sector in aligning its own planning and coordination with government priorities.
- *Contract management:* reinforcing the Deed of Agreement between the NBA and the Australian Red Cross Society, particularly by incorporating service standards, specifications for key deliverables, a more representative set of performance indicators against key elements of the Deed, and mechanisms for client feedback, would provide a clearer basis on which to manage fresh blood supply arrangements.
- *Program effectiveness:* establishing national systems, data specifications and evaluation strategies to measure the impact of blood safety measures and initiatives to promote the appropriate use of blood products on patient outcomes and blood sector efficiency. This would strengthen the NBA's reporting of the overall efficiency and effectiveness of the blood supply program.

27. The ANAO has made five recommendations to strengthen the NBA's administration of the blood supply program. These recommendations emphasise the importance of clear priority setting, stakeholder engagement, and sound contract management in defining and measuring program effectiveness. The recommendations encourage further blood sector efficiency, and are not intended to reduce the supply or quality of blood or blood services to patients in need, as a means of cost containment.

## Key findings by chapter

### Governance arrangements (Chapter 2)

28. The NBA was established as part of a coordinated national approach to policy setting, governance and management of the Australian blood sector, which was intended to secure access to safe and affordable blood services and products into the future. The NBA's governance arrangements are defined through the NBA Act and the National Blood Agreement. In addition, the NBA is expected to meet requirements defined in the Financial Management and Accountability (FMA) Act.

29. Since its establishment in 2003, the NBA has implemented organisational structures and operational frameworks that meet its specific legislative functions and broader government expectations. Its approach to conveying strategic priorities, however, is limited. There would be benefit in the NBA ensuring that its Corporate Plan is kept up to date and either enhancing the plan, or using another suitable vehicle, to develop and clearly convey to external stakeholders the NBA's medium to longer term priorities and activities, and how these link to broader government priorities. It would also be useful for such planning to identify mechanisms to measure the outcomes and effectiveness of government strategies, including recommendations from blood sector reviews and initiatives to improve blood sector safety and performance.

30. The NBA operates within a multijurisdictional environment with a governance hierarchy consisting of several levels of governing committees. This structure presents particular administrative complexities and, at times, can slow the progress and timely endorsement of significant policies, initiatives and key procedural documents. While acknowledging that review and modification of blood sector governance arrangements has occurred since the NBA's establishment, there would be benefit in NBA's governing committees working with the NBA to more clearly delineate its roles and

responsibilities, particularly the extent of involvement that the NBA should have in blood sector policy development and broader stakeholder engagement. Action in this area should help to improve the timeliness of progressing key work through the committees.

31. A key role for the NBA has been to facilitate and coordinate the implementation of a substantial change program in Australia's blood sector. The NBA has implemented a range of communication mechanisms across the many aspects of its business. Implementation of a more encompassing communication strategy with a broader-reaching approach to stakeholder consultation, would complement existing activities and enable the NBA to better inform the blood sector of longer-term planned activities. This would also facilitate feedback on the uptake, impact, costs and benefits associated with the governments' blood sector reforms.

### **Coordinating the blood supply (Chapter 3)**

32. A particular role of the NBA has been to facilitate the central coordination of the purchase of blood products and services. This approach was intended to provide greater efficiency in funding the blood supply and improve monitoring of the costs of blood services and products. It also promised to provide Australian governments insight into supply and wastage issues and to promote nationally consistent best practice in the use of blood products—matters which all contribute to the effectiveness and efficiency of the blood system.

33. To meet its legislative and national policy obligations, the NBA, as the central coordinating body, has established contracts to secure a sufficient blood supply consisting of a range of fresh blood, plasma-derived and recombinant products.<sup>15</sup> Processes are also in place for annual planning for the blood supply, including appropriate procedures for estimating the coming year's needs and budget and developing a National Supply Plan and Budget (NSPB).

34. These processes were generally successful, though at times more complicated than desired due to difficulties in coordinating around several different jurisdictional budget processes. The NSPB is reviewed mid-year, and supply estimates have generally met the specified targets. Given the substantial budget for each year's blood supply, there would be benefit in the

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<sup>15</sup> The NBA Act defines the NBA's functions. The National Blood Agreement defines the blood policy objectives within which the NBA operates, and roles and responsibilities of the parties to the Agreement.

NBA, JBC and the Department of Health and Ageing further streamlining the planning and coordination procedures to ensure timely endorsement of the NSPB by Ministers.

35. National policy recognises that Australia's blood supply needs to be affordable and the blood sector efficient. Significant rises in blood supply expenditure over the last decade are a risk to future affordability for governments. Published trends show a continuing rise in the costs of blood services and products, with total blood expenditure from 2003–04 to 2009–10 increasing by an average of 11.4 per cent per annum.

36. Fresh blood expenditure grew from \$243 million to \$456 million over the seven years to 2009–10, the NBA attributing the greatest proportions of this to price increases and the implementation of blood safety measures. While the reasons for rising safety costs were largely apparent, greater insight into the causes of increasing fresh blood product costs could assist the NBA, Australian governments and the broader sector to focus on cost saving and value for money strategies. To date, the impact of efficiency measures and strategies to enhance appropriate use or minimise wastage of blood products, and their influence on value for money or the cost-effectiveness of the blood supply, have not been measurable due to the lack of data and information available.

37. The NBA and ARCBS have invested considerable time and resources in reviewing the efficiency of the blood sector and implementing activities to improve many areas of ARCBS business, promote appropriate use of blood products and improve blood inventory, to list but a few. There is scope for the NBA, with the JBC and the Department of Health and Ageing (DoHA), to more fully consider data sets and evaluation strategies to gauge the broader cost implications of quality and safety measures, the cost-benefits of patient outcomes and any consequent savings.

#### **The Deed of Agreement between the NBA and ARCS (Chapter 4)**

38. The Deed of Agreement (the Deed) between the NBA and the ARCS documents the basis of arrangements for the supply of fresh blood, blood products and services by the ARCBS (the operational arm of the ARCS). This contractual arrangement constitutes almost half of the national blood supply budget each year, and is the most substantial of the NBA's contracts.

39. Negotiations towards the first Deed were lengthy; a 2006–09 Deed was signed some three years after the NBA's establishment. This was indicative of the complexities of the blood sector and the early relationship between the

NBA and the ARCBS, which reflected two very different cultures working within a complex blood sector—the ARCBS, which had existed in various forms for over 70 years, and the NBA, a recently established government body with an agenda that included blood sector efficiency reforms. Within this environment, the NBA and ARCBS established a Deed (subsequently extended to 2011), which provided an adequate rather than ideal basis for the national blood supply arrangements, due to inconsistent detail in its specifications for deliverables and a lack of service level standards.

40. As with other government service contracts, the arrangement with the ARCBS needs to demonstrate value for money: a concept that is not straightforward considering that the ARCBS is the sole provider of fresh blood to governments, and that estimating the value of health outcomes is intrinsically difficult. In line with government policy for efficiency and affordability of the blood supply, the 2006–09 Deed reflects a broad-sweeping change agenda, with a series of reviews and options for improving the efficiency of the blood supply—initiatives such as output-based funding to help contain expenditure, a national inventory system to monitor and forecast supply needs, and new testing measures to improve the safety of blood products.

41. While progress has been made in a number of key areas, the volume of activities to be undertaken through the 2006–09 Deed was ambitious and the priorities unclear. Furthermore, the early relationship between the NBA and ARCBS was not sufficiently mature to facilitate timely implementation of such a substantial change agenda. There would be benefit in taking a more strategic approach to managing the blood supply, including a thorough analysis of governments’ and the blood sector’s risks and needs, to inform the prioritisation of key activities for progression within agreed timelines.

42. The negotiations towards a new Deed provide both organisations with the opportunity to evaluate past experiences and use lessons learned to develop a stronger, mutually focused relationship. Useful improvements to the Deed would include:

- the inclusion of clearer specifications, roles and responsibilities for each key ARCBS function under the Deed;
- development of a more representative set of Key Performance Indicators (KPIs) and targets to measure qualitative as well as quantitative aspects of the contract deliverables. This is particularly important for areas of blood donor management and blood collection, testing, inventory and Transfusion Medicine Services; and



- establishing clear processes to engage with stakeholders, and measure and report client satisfaction.

## **Commercial contract management (Chapter 5)**

43. Although Australia is largely self-sufficient in fresh blood products, government policy allows the NBA to import blood products where Australia does not manufacture a particular product or where domestic production can not meet demand, as is the case for Intravenous Immunoglobulin (IVIg).

44. The NBA has established contracts with 10 commercial suppliers for a range of blood products (defined blood products) to meet Australia's needs. The ANAO examined the NBA's approach to procurement and contract management through the Baxter Healthcare Pty. Ltd. (Baxter) contract.

45. The NBA has taken appropriate steps to secure a contract with Baxter for the range of defined blood products required by the Australian governments. The procurement processes were conducted according to the Commonwealth Procurement Guidelines (CPGs).

46. Overall, the arrangements with Baxter have been effectively administered by the NBA, providing the required contract deliverables. There are, however, opportunities for the NBA to strengthen its contractual relationship with Baxter and future suppliers, for example, by:

- implementing risk plans, and monitoring and reporting against these;
- including a more structured dispute resolution process in contracts;
- planning and consulting about upcoming procurements earlier; and
- consulting external stakeholders more regularly and extensively.

## **Monitoring performance (Chapter 6)**

47. The reporting of progress and performance in accordance with the Government's outcomes and programs framework is an important mechanism by which public sector agencies can provide transparency and accountability of their operations to the Parliament and the public. Agencies are required to report the effectiveness of their program delivery against a set of KPIs which are aligned to an outcome, program activities and deliverables.

48. The NBA's 2010–11 Portfolio Budget Statement demonstrates an outcomes and programs structure which meets the outcome and program framework requirements. It also aligns with the primary policy objectives of

the National Blood Agreement and the roles and responsibilities specified in the NBA Act. The agency's performance indicators and deliverables for Program 1.1: *National Blood Agreement Management* align with its Major Activities:

- secure the supply of blood and blood products;
- risk management and sector performance improvement; and
- appropriate patient blood management and safe use of blood and blood products.

49. For all three Major Activities, the NBA identifies a key performance target as obtaining a 'high level of satisfaction' from its most significant client—the Jurisdictional Blood Committee (JBC).<sup>16</sup> Over time, the NBA has reported a high level of satisfaction from the JBC, however, when considering program or agency effectiveness, it would be useful for the NBA to seek the perspectives of a broader range of stakeholders, particularly as their perceptions and actions could impact on the success of blood program activities and broader outcomes.

50. The NBA assesses its program efficiency through various analyses of cost data. However, demonstrating and ensuring value for money in its blood supply functions requires additional information on the quality of the services and the impact of government measures to improve the use of blood products and reduce wastage over time. The transparency of NBA and ARCBS operations contributes to government and stakeholders' confidence in these organisations, which is important given the altruistic nature of Australia's blood donation/transfusion system. The establishment of national systems and data sets should help to improve blood sector transparency and better inform the NBA's performance monitoring, supply planning and value for money across the range of NBA's functional responsibilities. Notwithstanding this, information on the quality of blood services and the impact of government initiatives for blood sector improvements would be strengthened by the NBA:

- establishing mechanisms to help it assess the impact of new blood safety measures on patient outcomes and blood sector efficiencies; and

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<sup>16</sup> The JBC represents the Australian, state and territory governments' positions on blood policy, demand, supply planning, funding and product distribution.

- implementing an evaluation strategy to determine the impact of its Clinical Practice Guidelines.

## Summary of agency responses

51. Responses to the audit were received from the NBA, DoHA and Baxter Pty. Limited.

### The National Blood Authority

52. The NBA provided the following response to the audit.

The National Blood Authority (NBA) welcomes the findings of the audit that the NBA has established organisational structures and processes which allow us to carry out our governance responsibilities, play an effective central role in the national coordination of the blood supply and advance the efficiency and effectiveness of the sector. The audit has provided a good summary of the complex policy, historical context and multi-jurisdictional environment in which the NBA operates and the challenges that these bring to a small agency.

The NBA agrees to the five recommendations. Work to implement recommendations 3, 4 and 5 has progressed during the audit and remains an ongoing focus.

### The Department of Health and Ageing

Managing the supply of blood and blood products is a complex area particularly given the diversity of stakeholders and the shared funding arrangements between the Commonwealth and states/territories. The Department notes that there are a number of recommendations for which the NBA does not have sole responsibility and depend on co-operation of the states/territories and the public/private health sectors.

53. The response from Baxter Healthcare Pty. Limited, which comments on specific aspects of the audit report, is included in Appendix 1.

# Recommendations

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## Recommendation No. 1

### Para. 2.36

To assist key stakeholders in planning and coordinating their own efforts towards more mutual benefits for the blood sector, the ANAO recommends that the National Blood Authority (NBA):

- within the context of governments' policy objectives, clearly define the NBA's longer-term priorities and strategic directions; and
- build upon its existing range of communication activities to make its longer-term priorities and strategic directions more visible to key blood sector stakeholders.

**NBA response:** Agreed.

## Recommendation No. 2

### Para. 3.54

To support future blood supply affordability, the ANAO recommends that the NBA, in consultation with key stakeholders (including the ARCBS, JBC and DoHA), develop a strategy to encourage cost-efficiency across the blood sector. The strategy should clearly incorporate national priorities, key linkages between national policies and activities, and performance measures against medium and longer-term outcomes.

**NBA response:** Agreed.

**Recommendation  
No. 3****Para. 4.41**

The ANAO recommends that the NBA strengthen its approach to managing the Deed of Agreement with the ARCBS by:

- clearly identifying the responsibilities, deliverables and service standards for each primary function specified under the Deed;
- developing a more representative set of Key Performance Indicators (KPIs) and targets to measure qualitative as well as quantitative aspects of the contract deliverables; and
- agreeing realistic timeframes and priorities for developmental work or research specified as part of the Deed.

**NBA response:** Agreed.

**Recommendation  
No. 4****Para. 4.78**

To help inform the NBA's assessment of the ARCBS's performance under the Deed of Agreement, the ANAO recommends that the NBA, in consultation with the ARCBS, Approved Health Providers and other key stakeholder groups:

- develop and implement definitions for the various forms of blood product wastage, and a strategy explaining how wastage should be dealt with in terms of funding, responsibility, reporting and incident reduction; and
- employ periodic client surveys to provide information that will identify opportunities for service improvement and efficiencies.

**NBA response:** Agreed.

**Recommendation  
No. 5**

**Para. 6.46**

To strengthen the NBA's measurement and reporting of program effectiveness, including value for money, the ANAO recommends that the NBA:

- establish mechanisms to better determine the impact of new blood safety measures on patient outcomes and blood sector efficiencies; and
- develop clear strategies to determine the impact of governments' initiatives to promote appropriate use of blood and blood products (including Clinical Practice Guidelines), for example evaluation strategies.

**NBA response:** Agreed

# **Audit Findings**





# 1. Introduction

*This chapter provides an overview of the National Blood Authority and its role in ensuring a sufficient national blood supply. It also outlines the objective, scope and methodology of the audit.*

## Supply of blood and blood products in Australia

**1.1** Human blood is a vital national resource and an integral component of Australia’s medical support system. Blood and blood products (Table 1.1) are used to treat people with a range of clinical conditions, including cancer patients, individuals who have suffered traumatic accidents, burns or are undergoing surgery, and to treat blood disorders such as haemophilia.<sup>17</sup>

**Table 1.1**

### Types of blood products

<b>Fresh blood components</b> Fresh blood includes both whole blood and its components, such as red blood cells, plasma and platelets. Plasma is commonly used to treat shock, burns or surgery, and platelets promote blood clotting.	<b>Plasma-derived products</b> Plasma-derived products include albumin, immunoglobulin and coagulation factors, which are all protein products fractionated and processed from plasma. Plasma-derived products are used to treat conditions including bleeding disorders and immune deficiencies.
<b>Recombinant products</b> Recombinant products are genetically engineered forms of plasma proteins, not produced from blood. The most commonly used recombinant blood products are Factors VIII, VIIa and IX (clotting factors largely used to treat haemophilia patients).	<b>Diagnostic reagents</b> Diagnostic reagents are products that are used for in-vitro diagnostic processes (blood tests), for example, ABO group testing and antibody screening. They include quality control reagents for use in transfusion and blood banking laboratories.

Source: National Blood Authority, National Blood Supply Contingency Plan—Blood and Blood Product Management, 2008.

Note: Also see Appendix 2 for a more detailed list.

**1.2** It is estimated that one in three Australians will require blood or blood products in their lifetime.<sup>18</sup> Maintaining an adequate and safe blood supply is therefore of vital importance. To a large extent, the national supply of blood depends on the goodwill of Australians, with around 520 000 (or about one in

<sup>17</sup> In Australia, blood donors are non-remunerated.

<sup>18</sup> Australian Red Cross Blood Service (ARCBS) <[www.donateblood.com.au](http://www.donateblood.com.au)> All about blood [accessed 19 August 2009]; and ARCBS Strategic Plan [accessed June 2011].

30) Australians donating their blood through the Australian Red Cross Blood Service (ARCBS) each year.

**1.3** Under the current arrangements, blood donors are not remunerated and patients receive blood and blood products free of charge. Blood components have a short shelf life, so their supply needs to be constant and able to meet clinical demand.<sup>19</sup> At times of national emergency the demand for blood and blood products may increase, or the supply may decrease, emphasising the importance of sound national planning and coordination of supply.

**1.4** Since July 2003, the National Blood Authority (NBA) has been responsible for the national planning and coordination of Australia's blood supply, including the purchasing of blood and blood products on behalf of the Australian, state and territory governments. These governments are party to a National Blood Agreement, under which they are jointly responsible for establishing the policy framework for the national blood supply and oversight of the NBA (also see paragraph 1.14).

## **The National Blood Authority**

**1.5** The NBA was established as a statutory agency under the *National Blood Authority Act 2003* (NBA Act),<sup>20</sup> following the government-initiated *Review of the Australian Blood Banking and Plasma Product Sector*.<sup>21</sup> It is an agency of less than 50 staff<sup>22</sup>, which operates under the *Financial Management and Accountability Act 1997* (FMA Act) and the *Public Service Act 1999*. The NBA is part of the Australian Government's Health and Ageing portfolio and has one Outcome.

### **NBA Outcome**

Access to a secure supply of safe and affordable blood products, including through national supply arrangements and coordination of best practice standards within agreed funding policies under the national blood arrangements.<sup>23</sup>

<sup>19</sup> For example, platelets have a shelf life of up to 5 days, red cells of up to 42 days and plasma up to one year. From <[www.donateblood.com.au/all-about-blood/how-donated-blood-used](http://www.donateblood.com.au/all-about-blood/how-donated-blood-used)> [accessed 15 March 2011].

<sup>20</sup> The NBA Act specifies that 'the NBA does not have a legal identity separate from the Commonwealth'.

<sup>21</sup> op. cit. The Stephen Review, 2001.

<sup>22</sup> The NBA Annual Report 2009–10 states that at 30 June 2010 the NBA had 48 staff. The NBA advised the ANAO during the audit that it had 46.6 Full-Time Equivalent staff.

<sup>23</sup> *Health and Ageing, Portfolio Budget Statements 2009–10*, p. 621.

**1.6** Section 8 of the NBA Act defines the NBA’s functions. The National Blood Agreement also articulates the NBA’s roles and responsibilities (Appendix 3) and lists the Australian governments’ policy objectives for the blood sector. The NBA’s strategic directions are articulated through its Portfolio Budget Statement. The NBA’s 2006–09 Corporate Plan specified its roles as follows.

**Table 1.2**

**National Blood Authority roles**

1. Coordinate national demand and supply planning of blood and blood products and purchase those products on behalf of all Australian governments	2. Implement an efficient demand driven system, based upon evidence and good clinical practice, so that the blood supply system is highly responsive to needs
3. Negotiate and manage contracts on behalf of all states and territories and the Australian Government with suppliers of blood and blood products to enable the development of an agreed single national pricing schedule	4. Work in a collaborative manner with all governments and other responsible parties to ensure that Australia’s blood supply is adequate, safe, secure and affordable

Source: ANAO, from information in the National Blood Authority Corporate Plan 2006–09, p. 2.

**1.7** One of the NBA’s major tasks is establishing contractual arrangements with providers of blood and blood products to ensure supply, improve blood sector performance and obtain information on product usage. This includes arrangements with the Australian Red Cross Blood Service (ARCBS) which is a division of the Australian Red Cross Society (ARCS)<sup>24</sup>, CSL Limited<sup>25</sup> and a range of other commercial manufacturers of blood products.

**The Australian blood sector**

**1.8** The NBA works within the context of the broader blood sector, a complex multi-jurisdictional environment consisting of government and non-government entities. The blood sector includes: the Australian, state and territory governments; private and public hospitals; pathology services; clinicians; blood donors; recipients of blood and blood products; and groups with particular needs, for example, the Haemophilia Foundation of Australia.

<sup>24</sup> ARCS is a not-for-profit humanitarian organisation.

<sup>25</sup> Formally the Commonwealth Serum Laboratories, CSL was incorporated in 1991 and listed in the Australian Stock Exchange in 1994. Australian-based, CSL fractionates plasma from blood collected by the ARCBS and supplies a range of plasma products (NBA Annual Report 2009–10, p. 22).

**1.9** There is considerable diversity of views and competing priorities within the blood sector, reflecting the multiplicity of entities within it. The NBA is dependent on its broad array of stakeholders to inform a range of activities, including the NBA's supply planning, sector improvement and coordination of better practice and risk management practices.

**1.10** Historically, a key facilitator and service provider in Australia's blood sector has been the ARCS, particularly through its operational division, the ARCBS. Over many decades the ARCS and ARCBS established a donor system based on voluntary and non-remunerated donations of blood. Under government arrangements, this system has delivered to Australians blood products which, by world standards, are of a high quality. The ARCBS has accumulated knowledge and insight into Australia's needs, the logistics of supply and demand, and the appropriate and efficient use of blood products.

**1.11** The Deed of Agreement between the NBA and ARCS is an important mechanism for facilitating a beneficial relationship between the ARCS/ARCBS and Australian governments for promoting continuous improvement of the national blood supply.

**1.12** Many factors influence the machinery and character of Australia's blood sector and the NBA's operations within that sector. These include:

- the legacy and complexity of the blood sector's governance arrangements, including the long-established and monopolistic position of the Australian Red Cross Blood Service (ARCBS) in Australia;
- the position of CSL as the fractionator of Australian plasma and the primary supplier of plasma products in Australia;
- increased demand and emerging trends for blood and blood products, and the resulting rise in blood supply expenditure;
- non-uniformity of blood sector operations across states and territories;
- nationalisation of the ARCBS in 1996<sup>26</sup>;
- the governments' policy objectives for the Australian blood sector, which include promoting self-sufficiency;
- the Australian Government's exemption of plasma and plasma-derived products from the Commonwealth Procurement Guidelines (CPGs);
- the Australia–United States Free Trade Agreement with overseas manufacturers seeking markets in Australia;
- the role of the Therapeutic Goods Administration (TGA) in the regulation of blood products; and
- a heightened awareness of product safety issues by governments, clinicians and patients following the publicised HIV and Hepatitis C risks to the blood supply in the 1980s and 1990s.

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<sup>26</sup> ARCS, *Annual Report 2008–09*, p. 13.

**1.13** These factors create a challenging environment in which the NBA has to meet its legislative responsibilities and attain its portfolio outcome. Implementing national blood policy and planning for the blood supply can be a complex and prolonged process. A systematic and well coordinated approach to governance is therefore required; one that allows for informed consideration of blood sector risks, drivers of future costs, key stakeholder needs, domestic and international trends and emerging treatments and products.

### **Current governance framework**

**1.14** As previously mentioned, the Australian, state and territory governments are all party to a National Blood Agreement<sup>27</sup>, which specifies the primary roles and responsibilities of the key decision-makers in the Australian blood sector. Under the Agreement, the states and territories have primary responsibility for optimising the management and use of blood and blood products once supplied to the health sector, specifically:

- establishing the policy framework and specific policies relating to the national blood supply;
- overseeing the NBA's management of blood supply arrangements;
- fostering the development and implementation of best practice systems to promote efficient use and minimal wastage of blood and blood-related products;
- providing information on demand for blood and blood-related products; and
- managing local issues.

**1.15** The Australian Health Ministers Council (AHMC) has ultimate oversight of the blood sector and sets the governance, policy and financial framework within which the NBA operates.

**1.16** The Australian, state and territory governments are represented on the Jurisdictional Blood Committee (JBC)—an established subcommittee of the AHMC.<sup>28</sup> The JBC acts as a conduit between governments and the NBA and is responsible for jurisdictional issues relating to blood supply. This includes planning annually for the supply needs and costs for each state and territory.

**1.17** The NBA Act established the NBA as part of a coordinated national approach to policy setting, governance and management of the Australian

<sup>27</sup> Approved by AHMC in 2002; <[www.nba.gov.au/about/background.html](http://www.nba.gov.au/about/background.html)> [accessed 9 October 2009].

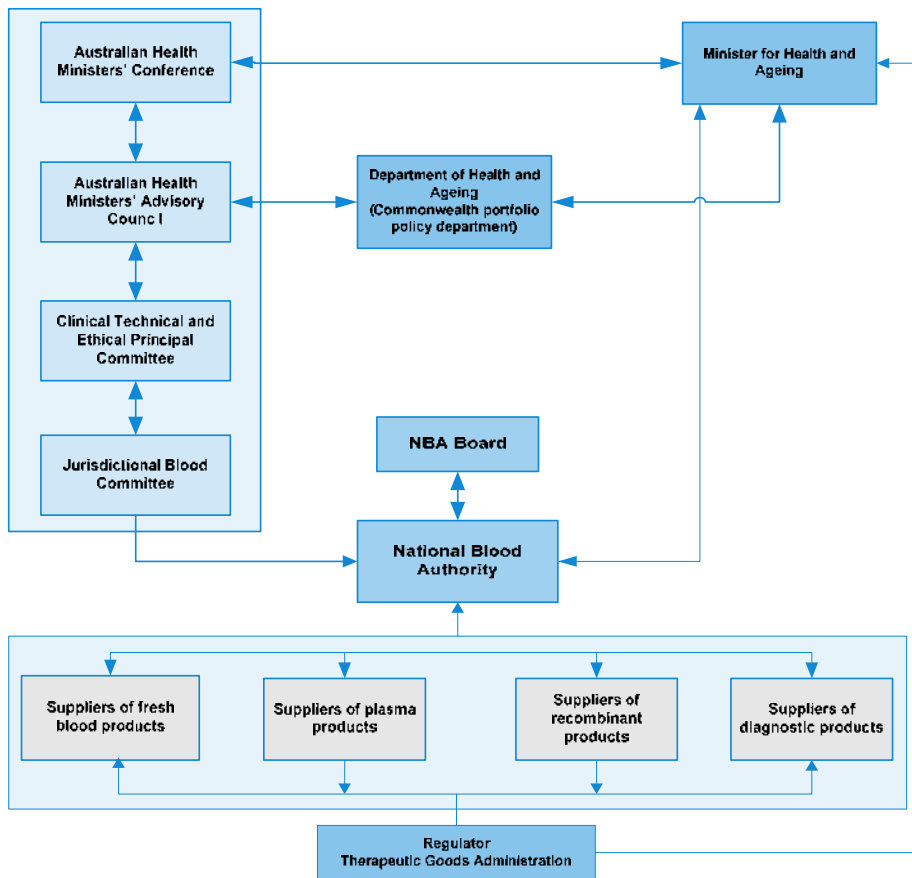
<sup>28</sup> In 2003 this was a subcommittee to AHMAC but now it reports to CTEPC—one of five principal sub-committees of AHMAC.

blood sector in line with the National Blood Agreement.<sup>29</sup> The NBA undertakes a secretariat role to the JBC and, in accordance with the NBA Act, represents the interests of Australia’s Commonwealth, state and territory governments when negotiating and managing contracts with providers of blood products and services.

1.18 The current governance framework for Australia’s blood sector, and the NBA’s position in this, is illustrated below.

Figure 1.1

**Australian blood sector governance**



Source: National Blood Authority, *Annual Report, 2008–09* p.22, adapted by the ANAO.

Notes: The Department of Health and Ageing is the Commonwealth portfolio department with blood policy responsibility and is also the secretariat to AHMC.

<sup>29</sup> *National Blood Authority Act 2003*, section 4.

## Funding of blood and blood services

**1.19** Funding for the NBA's coordination and purchasing activities is multi-jurisdictional, with the Australian Government contributing 63 per cent and the states and territories 37 per cent of total funding. Funds for blood supply contracts are managed by the NBA through a special account specified under the NBA Act.

**1.20** Since the NBA was established in 2003, Australian governments have spent \$4.6 billion on blood and related products and \$64 million on the operation of the NBA.<sup>30</sup> Table 1.3 shows NBA appropriations for 2009–10 and 2010–11.

**Table 1.3**

### NBA appropriations for 2009–10 and 2010–11

Budget component	Total Estimate 2009–10 (\$)	Total Estimate 2010–11 (\$)
Departmental Outputs	5.5 million	5.6 million
Administered Expenses	7.7 million	5.7 million
Special Account (blood Supply Contracts)	1.1 billion	1.2 billion

Source: NBA Portfolio Budget Statements 2009–10, p. 615; and 2010–11, p. 691.

**1.21** Over the period 2003–2010, total blood costs rose by an average of 11.4 per cent per annum<sup>31</sup>, due to increasing demand for blood and blood products, the introduction of safety measures and price rises.

## NBA contracting arrangements

**1.22** All blood products supplied under the National Blood Agreement are purchased under contracts negotiated and managed on behalf of all governments by the NBA. The NBA's management of contracts, therefore, enables the development of an agreed single national pricing schedule.

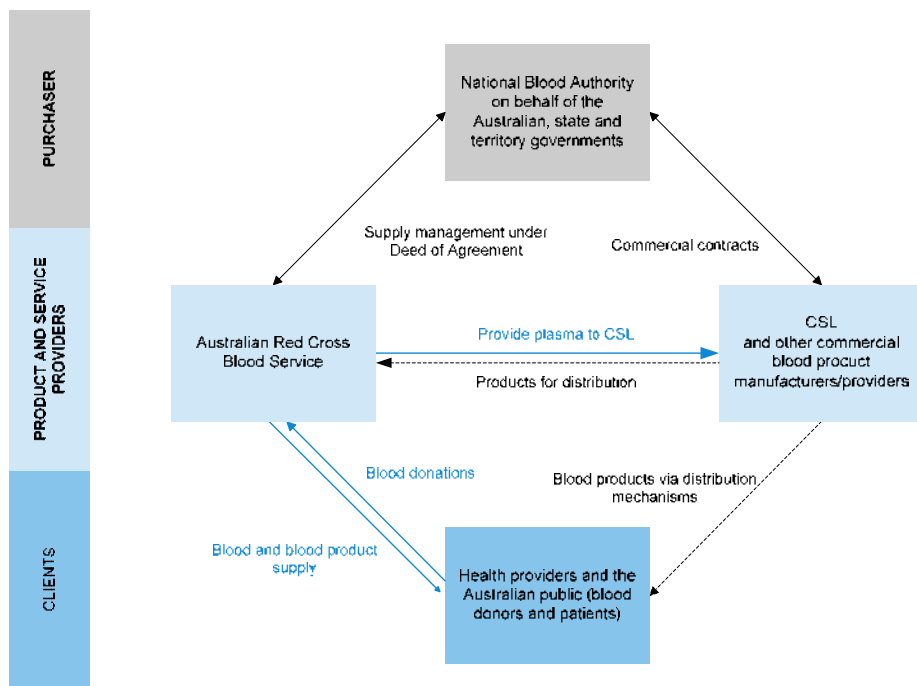
**1.23** Figure 1.2 illustrates the relationship between the NBA (the purchaser), the manufacturers and providers of blood and blood products and the ultimate clients (the Australian public who are both the donors and users of blood).

<sup>30</sup> op. cit., NBA Annual Report 2009–10, pp. 21 and 22.

<sup>31</sup> ibid., p. 21.

**Figure 1.2**

**Purchaser–provider arrangements for Australia’s blood supply**



Source: ANAO.

**1.24** In 2009–10 the NBA had 14 contracts for the supply of blood or blood products, with expenditure totalling \$879 million (Table 1.4). The NBA has a substantial contract with the ARCS, which in 2009–10 provided \$456 million for essential blood supply services to support the Australian health system.<sup>32</sup>

**1.25** Under the NBA–ARCS Agreement (which is currently under renegotiation) the ARCS is required to ‘collect, manufacture and distribute fresh blood products from voluntary donations, and distribute plasma products and imported blood products to hospitals and other users in Australia.’<sup>33</sup> The ARCS generates data that informs the NBA’s supply planning and, through its Transfusion Medicine Services (TMS), promotes best practice by providing advice to medical professionals on the appropriate use of blood and blood products.

<sup>32</sup> *ibid.*, pp. 21, 44 and 45.

<sup>33</sup> <[www.nba.gov.au/pubs/factsheets.html](http://www.nba.gov.au/pubs/factsheets.html)> New Deed of Agreement between NBA and ARCS [accessed 19 August 2009].



Table 1.4

## Suppliers contracted to NBA in 2010 to provide blood and blood products

Contracted Supplier	Contract subject matter	Original duration of current contract	Contract extension (where applicable)	Total funding (\$) across term of contract including extension periods
<b>Australian Red Cross Society</b>	Supply of blood and blood related products and services by the ARCBS	1 September 2006 to 30 June 2009	Extended twice until 30 June 2011 <sup>34</sup>	2 323.8 million
	Related governance costs	1 July 2008 until 30 June 2009	Extended to 30 June 2011	1.1 million
	NSW/ACT Principal Site Deed of Indemnity	2009 until 2031.	N/A	116 million
	Funding Agreement for the ARCBS Victoria/Tasmania Principal Site (VTPS)	11 March 2010 until 1 September 2031	N/A	99.0 million
<b>CSL Limited</b>	Fractionation and supply of plasma products	1 January 2010 until 31 December 2017	N/A	2 441.6 million
	Supply of diagnostic reagent products	1 November 2007 to 31 October 2009	Extended twice until 30 June 2011	9.9 million
<b>Baxter Healthcare Pty Ltd</b>	Supply of Defined Blood Products	1 July 2006 until 30 June 2009	Extended to 30 June 2011	517.5 million
<b>Pfizer Australia Pty. Ltd. (formerly Wyeth Australia Pty Ltd)</b>	Supply of Defined Blood Products	1 July 2006 until 30 June 2009	Extended to 30 June 2011	259.4 million
<b>Novo Nordisk Pharmaceuticals Pty Ltd</b>	Supply of Defined Blood Products	1 July 2006 until 30 June 2009	Extended to 30 June 2012	155.7 million
<b>Octapharma Australia Pty Ltd</b>	Supply of imported IVIg products	1 December 2007 to 31 December 2009	Extended twice until 31 December 2011	116.8 million
<b>Laterol Grifols Ltd (formerly DiaMed Australia Pty Ltd)</b>	Supply of imported IVIg products	1 January 2010 to 31 December 2012	N/A	9.0 million
	Supply of diagnostic reagent products	1 November 2007 to 31 October 2009	Extended twice until 30 June 2011	2.8 million
<b>Ortho-Clinical Diagnostics (Johnson &amp; Johnson Company)</b>	Supply of diagnostic reagent products	1 November 2007 to 31 October 2009	Extended twice until 30 June 2011	1.5 million
<b>Abacus ALS Pty Ltd</b>	Supply of diagnostic reagent products	1 November 2007 to 31 October 2009	Extended twice until 30 June 2011	0.1 million

Source: NBA website, <[www.nba.gov.au/compliance/contracts.html](http://www.nba.gov.au/compliance/contracts.html)> [as at 22 March 2011]; and updated NBA advice provided to the ANAO on 21 June 2011.

<sup>34</sup> The ARCBS advised that the Deed has been further extended until 15 December 2011.

**1.26** The NBA's implementation of contracts and associated supply and contract management issues occurs within the policy and financial framework agreed to by all governments. In executing this role, the NBA must translate government priorities and policies into contractual requirements for providers such as the ARCS and commercial manufacturers, while also maintaining sound contract management principles and meeting the legislative requirements of the NBA Act and the FMA Act.

**1.27** Of the 14 NBA-managed contracts for the blood supply, the ARCS/ARCBS and CSL Limited contracts represent around 75 percent of the NBA's blood supply contract funding for 2009–10.

### **Contracting and value for money considerations**

**1.28** The NBA's contracting for blood products is complex. The NBA has two main arms to its contractual arrangements: the ARCS, which is a monopoly supplier of fresh blood products to governments; and pharmaceutical companies that operate in a more competitive environment. Of the commercial providers, CSL Limited is currently the only plasma fractionator within Australia. Most plasma products used in Australia are manufactured by CSL under the CSL Australian Fractionation Agreement from plasma provided by the ARCBS.<sup>35</sup> Where Australia imports plasma products, the agreements are intended to ensure security of supply and reserve stocks, in line with government policy.<sup>36</sup>

**1.29** As an FMA Act agency, the NBA is required to use Commonwealth funds in an effective and efficient manner, demonstrating value for money. The 'procurement of blood plasma products or blood fractionation services', is exempt from the Mandatory Procurement Procedures (MPPs) of the Commonwealth Procurement Guidelines (CPGs), although the principle of value for money still applies.<sup>37</sup>

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<sup>35</sup> The *Review of Australia's Plasma Fractionation Arrangements* (the Flood Review), 2006, concluded that the processing of Australian blood for plasma products would remain in Australia. The review was undertaken as part of the Australia–United States Free Trade Agreement.

<sup>36</sup> Importation may occur where a product is low-volume and therefore not produced within Australia, where clinical demand exceeds local capacity to provide the product, or in providing Standing Offers for contingency supplies to supplement domestic supply (for example, immunoglobulin).

<sup>37</sup> *Commonwealth Procurement Guidelines*, 2008, p. 41. Procurement of blood plasma products or plasma fractionation services are exempt from the Mandatory Procurement Procedures, however are still required to be undertaken in accordance with the principles of value for money and with the requirement of Division 1 of the CPGs.

**1.30** A key challenge for the NBA is achieving value for money in a sector with sole or a limited range of suppliers in accordance with the:

- Australian Government's procurement framework; and
- policy objectives of the National Blood Agreement, including promoting self-sufficiency.

## Previous audit coverage

### Performance audit

**1.31** This is the ANAO's first performance audit of the NBA. Three performance audits concerning plasma fractionation and contract management with CSL were previously conducted in the Department of Health and Ageing (DoHA) and the former Department of Health and Aged Care (DHAC). The current audit does not include an assessment of the contractual arrangements with CSL.

## Audit objective and scope

### Objective

**1.32** The audit objective was to assess whether the NBA's governance and contractual arrangements are effective in securing a national supply of blood products and services.

### Audit scope

**1.33** The scope of the audit included the NBA's governance and operational arrangements to meet the functions of the NBA Act and Government policy. The audit encompassed the NBA's coordination with the blood sector, including relationship management, assessment and planning for the national blood supply, key contracting requirements, information and data management and the NBA's approach to measuring performance against its key objectives and Outcome.

**1.34** Particular emphasis was given to the NBA's management of the Deed of Agreement with the ARCS 'for service arrangements' provided by the ARCBS, the largest of the NBA's blood supply contracts.<sup>38</sup>

**1.35** The audit did not include an examination of the Therapeutic Goods Administration (TGA) and associated quality assurance activities, the NBA's contracts with CSL or CSL functions (unless directly part of the NBA-ARCS Deed of Agreement or NBA supply plan and budget), or a detailed assessment of the broader blood sector.

## **Audit methodology**

**1.36** To achieve the audit objective, the ANAO assessed the NBA's performance against three major criteria—that the NBA:

- demonstrates sound governance and administrative systems to support blood and blood product supply, including arrangements to assess and consider value for money;
- uses accountable and responsive contract management practices, to meet legislative requirements, government policy and national supply needs; and
- undertakes performance monitoring which measures the effectiveness of contractual arrangements and informs higher level outcomes relating to the quality, reliability and appropriate use of the national blood supply.

**1.37** Audit fieldwork was undertaken primarily at the NBA, and included the examination of files and electronic records and evaluation of key processes against legislative, policy and contractual requirements. The ANAO consulted stakeholders in three states, including representatives of the state health departments, Approved Health Providers (hospitals in receipt of blood and blood products), the ARCBS and blood sector committees. Discussions were also held with officers in the TGA and other areas of DoHA.

**1.38** The audit was conducted in accordance with ANAO Auditing Standards and utilised the ANAO Better Practice Guides in audit design and analysis.<sup>39</sup> The audit was completed for a total cost of \$583 051.

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<sup>38</sup> The Deed of Agreement between the National Blood Authority (on behalf of the Commonwealth) and the Australian Red Cross Society (ARCS) 2006–09.

## Report structure

**1.39** The report has the following structure:

Chapter	The chapter examines:
1 Introduction	<i>The NBA and its role in ensuring a sufficient national blood supply. It also outlines the objective, scope and methodology of the audit.</i>
2 Governance Arrangements	<i>The NBA's role in Australia's blood sector and the governance arrangements that enable the NBA to carry out its functions and responsibilities to the Australian, state and territory governments.</i>
3 Coordinating the Blood Supply	<i>Performance of the NBA in coordinating the national blood supply, including measures to improve the cost-effectiveness of blood product purchase and appropriate usage.</i>
4 The Deed of Agreement between the NBA and the ARCS	<i>Contractual arrangements between the NBA and the Australian Red Cross Society (ARCS) for the provision of fresh blood products and services through the Australian Red Cross Blood Service (ARCBS).</i>
5 Commercial Contract Management	<i>The NBA's approach to managing commercial contracts, using the example of its contract with Baxter Healthcare Pty Ltd for the supply of Defined Blood Products.</i>
6 Monitoring Performance	<i>The NBA's approach to monitoring and reporting its performance, and the data capacity supporting these activities.</i>

<sup>39</sup> ANAO, Better Practice Guide—*Developing and Managing Contracts*, February 2007; ANAO, Better Practice Guide—*Fairness and Transparency in Purchasing Decisions*, August 2007; and ANAO, Better Practice Guide—*Public Sector Governance*, July 2003.

## 2. Governance Arrangements

This chapter examines the NBA's role in Australia's blood sector and the governance arrangements that enable the NBA to carry out its functions and responsibilities to the Australian, state and territory governments.

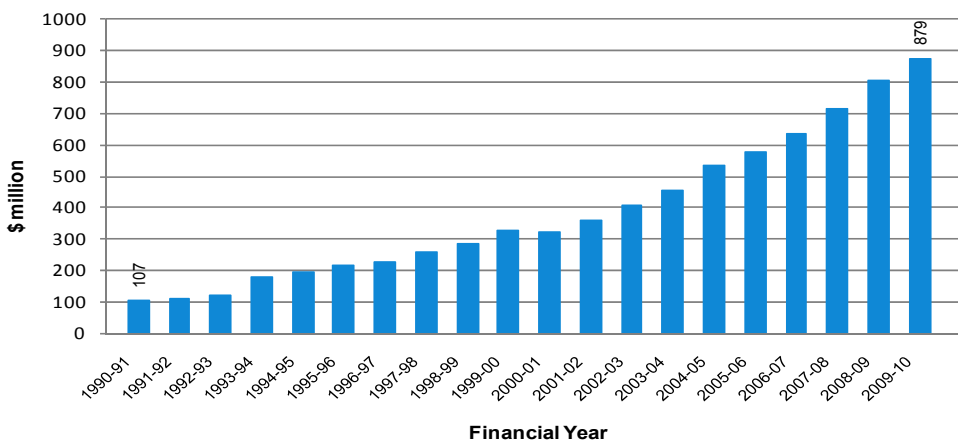
### The establishment of the National Blood Authority

**2.1** The National Blood Authority (NBA) was established under the *National Blood Authority Act 2003* (NBA Act) as 'part of the coordinated national approach to policy setting, governance and management of the Australian blood sector as agreed under the National Blood Agreement'.<sup>40</sup>

**2.2** This coordinated approach was intended to address a number of issues identified through the Stephen Review (2001), which examined Australia's blood banking and plasma product sector. Among other matters, the review made recommendations to address inefficiencies in the blood sector, the lack of coordination and national focus, and the rising cost of blood products and services—which had almost tripled between 1991 and 1999 (Figure 2.1).<sup>41</sup>

**Figure 2.1**

#### Cost of blood products and services in Australia 1990 to 2010



Source: NBA *Portfolio Budget Statements 2009–10* and *2010–11*; data provided by the NBA for 2000–2003; and Stephen Review 2001, p. 161.

<sup>40</sup> *The National Blood Authority Act 2003*, section 4 Main Purpose of this Act, p. 3.

<sup>41</sup> *op.cit.*, The Stephen Review, 2001.

**2.3** With blood supply costs steadily rising, Australian governments recognised the need for additional vigilance to inform efficiency measures without impeding blood sector improvements or the safety and availability of blood products and services. In establishing the NBA, they sought to enhance the efficiency of the blood supply by centralising the purchase of blood products and services. As the national coordinating body, the NBA would be better positioned to monitor the price, quality and demand of blood products and services on behalf of the Australian, state and territory governments.

**2.4** National coordination remains an imperative of governments given the crucial importance of the blood supply to the health of Australians and the substantial funds required to ensure supply—an estimated national budget of \$1 billion in 2010–11.<sup>42</sup>

### **Establishing appropriate governance arrangements**

**2.5** The NBA is required to meet the specifications of its enabling Act, as well as broader Australian Government legislation including the *Financial and Management Accountability Act 1997* and *Public Service Act 1999*. Given the agency's substantial budget, it is important that the NBA has a sound system of governance to enable the efficient, effective and accountable use of Commonwealth funds.

**2.6** Governance structures and processes must also support these principles and facilitate: the NBA's planning and execution of key functions to meet its agency and program outcome; and the appropriate endorsement and timely implementation of government policy as prescribed under the National Blood Agreement (see Appendix 3).<sup>43</sup>

**2.7** The NBA's key functions include: blood supply planning, funding and contracting; national coordination and facilitation of policy development, information and advice to the ministers; and measures concerning the safety, quality, contingency and risk mitigation for the supply of blood products and services.<sup>44</sup> One of the aims in establishing the NBA was 'to ensure the

<sup>42</sup> *Health and Ageing Portfolio Budget Statements 2009–10*, p. 625. This figure includes annual administered expenses and program support.

<sup>43</sup> The NBA is also expected to operate in accordance with the Australian Government's outcomes and program framework, which supports program transparency and reporting to parliament. This is assessed in Chapter 6.

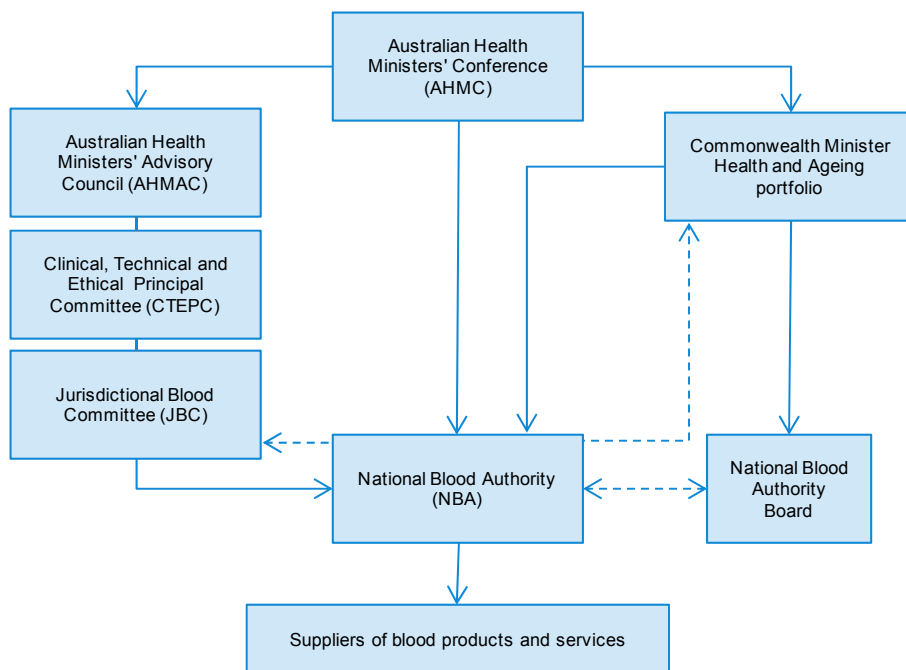
<sup>44</sup> op.cit., NBA Act p. 4, section 8.

continuation and safety of our blood system for present and future generations of Australians'.<sup>45</sup> Making progress towards such strategic goals is an important role for the NBA's internal governance and its external governing bodies.

2.8 Figure 2.2 illustrates the oversight arrangements for the management of Australia's blood sector and the NBA's relationship with Australian governments, ministers and cross-jurisdictional committees.

**Figure 2.2**

**The NBA's position in blood sector governance**



Source: ANAO.

Note 1: Oversight role is represented by unbroken arrows and the provision of advice, information and/or support between entities is shown by broken arrows.

Note 2: The Department of Health and Ageing (DoHA), though not shown in this figure, also has a role in the blood sector through its role in the development, funding and implementation of health policy and programs, and the broader portfolio management and reporting responsibilities of the DoHA Secretary.

2.9 The ANAO examined the NBA's internal and external governance arrangements to determine if these supported the NBA in operating in an

<sup>45</sup> House of Representatives, Second Reading Speech, Mr Alex Somlyay MP, Wednesday 26 March 2003, pp. 13626–8.



efficient and effective manner, to meet the expectations of Australian governments. The assessment covered:

- the NBA's roles and functions;
- broader blood sector governance arrangements;
- the NBA's role in managing change in the blood sector; and
- priority setting for the longer term.

## NBA roles and functions

**2.10** To execute its role in the national coordination of the blood supply and management of Australia's blood sector, the NBA is required to perform the ten functions listed in section 8 of the NBA Act.

- a) To liaise with, and gather information from, governments, suppliers and others about matters relating to blood products and services;
- b) to carry out national blood arrangements relating to annual plans and budgets for the production and supply of blood products and services;
- c) to carry out national blood arrangements to ensure sufficient supply of blood products and services in all the states and covered territories;
- d) to carry out national blood arrangements relating to the funding of (i) the supply of blood products and services and (ii) the NBA operations;
- e) to enter and manage contracts and arrangements for the collection, production and distribution of the blood products and services...;
- f) to carry out national blood arrangements relating to safety measures, quality, contingency measures and risk mitigation measures for the supply of blood products and services;
- g) to provide information and advice to the Minister and the Ministerial Council about matters relating to blood products and services;
- h) to carry out national blood arrangements relating to the facilitation and funding of research, policy development and other action about matters relating to blood products and services;
- i) to provide assistance (i) in accordance with national blood arrangements, to a committee referred to in those arrangements; and (ii) to the Board and (iii) to the advisory committees (if any) established under section 38; and
- j) such other functions (if any) as are determined by the Ministerial Council and specified in written notice given by the Minister to the NBA.

**2.11** Since its inception, the NBA has established internal governance arrangements to allow it to carry out these functions. These are reflected in the NBA's organisational structure, corporate plans and operational frameworks to various degrees. Each year, the agency sets out in its Portfolio Budget Statements the framework in which its primary functions will be executed. This framework includes key performance indicators and strategies against the program outcome (also see Chapter 6). Table 2.1 provides an assessment of the NBA's higher-level planning and procedural arrangements, against key governance requirements.

**Table 2.1**

**Assessment of the NBA against key governance requirements**

Governance requirement/criteria	ANAO assessment
<b>The agency has in place:</b>	
<p><b>Clear roles and responsibilities</b></p> <p>The NBA's roles and responsibilities are clearly defined and are in line with legislative and policy obligations.</p>	<p><b>Largely met.</b> The NBA Act defines the NBA's functions, and the roles and the responsibilities of the agency, the General Manager and the Board. While the NBA's accountability is ultimately to the Commonwealth Minister, it also has responsibilities to the states and territories and the Jurisdictional Blood Committee under the National Blood Agreement. While legislative functions are undertaken, the extent of the NBA's policy development responsibilities and the respective roles of the JBC and Department of Health and Ageing (DoHA) could be more precisely defined by the parties.</p>
<p><b>Risk management processes</b></p> <p>Up-to-date plans are in place, appropriately endorsed, accessible, and address risks at all levels of program administration.</p>	<p><b>Met.</b> The NBA has developed a well structured and comprehensive range of risk management guidelines and materials which are accessible to its staff. The NBA developed a Business Continuity Plan in 2006–07 and in 2008–09 its National Blood Supply Contingency Plan was endorsed. Identification and mitigation of risk is considered for each project.</p>
<p><b>Strategic/corporate planning</b></p> <p>The NBA has established planning processes which reflect key government policies and priorities. The corporate plan includes outcomes, objectives, key strategies and performance indicators.</p>	<p><b>Largely met for corporate planning; partially met for longer-term strategic elements.</b> Section 43 of the NBA Act requires the NBA to have a corporate plan endorsed by the minister. The NBA's last corporate plan was dated 2006–09. This was rolled over for 2009–10. The NBA advised that a new plan was with ministers for signing in September 2011.</p> <p>While the NBA had a number of forward-looking program initiatives underway, strategic planning could be strengthened by clearer definition of the NBA's and its governing committees' responsibilities in strategic matters and more open communication to stakeholders of the NBA's long-term strategies to address key blood priorities.</p>
<p><b>Procedural documentation</b></p> <p>NBA procedures are documented and accessible to staff.</p>	<p><b>Met.</b> The NBA has processes and supporting documentation for key activities, including the development and implementation of its National Supply Plan and Budget, an annual operational plan and extensive contracting arrangements. The NBA's Intranet provides staff with ready access to a set of Chief Executive Instructions, Procedural Rules and guidance materials for key business processes.</p>
<p><b>An internal audit committee and an audit program</b></p>	<p><b>Met.</b> The NBA has an audit committee and a planned schedule of audits.</p>
<p><b>A framework for conducting and implementing program review and evaluation</b></p> <p>Recommendations from reviews and evaluations are implemented as required, to facilitate continuous program improvement.</p>	<p><b>Largely met.</b> The NBA reports progress in the implementation of reviews through JBC to AHMC. Several planned reviews have been conducted since the NBA was established, and these have provided the NBA (and the government's broader governing bodies) with direction to improve the effectiveness and efficiency of the blood sector. However, a more systematic process to evaluate the benefits or savings from the initiatives stemming from reviews is needed.</p>
<p><b>Annual reporting</b></p> <p>In accordance with the government requirements and best practice.</p>	<p><b>Met.</b> The NBA has produced informative Annual Reports over the life of the agency. To ensure transparent and balanced annual reporting, it is important that the NBA report on areas where its progress against planned targets or timeframes was not achieved as well as those where it was.</p>

Source: ANAO analysis against criteria developed from: ANAO Better Practice Guide—*Public Sector Governance*, July 2003, pp. 13–27; NBA Act 2003; and the National Blood Agreement.

**2.12** In general, the NBA's internal governance arrangements demonstrate a sound understanding of governance requirements and the principles that apply to public sector agencies. Notwithstanding this, the NBA's corporate/strategic planning processes should ensure that an up-to-date Corporate Plan is in place (as required by section 43 of the NBA Act). There would also be benefit in defining longer-term priorities and strategies in relation to the blood sector more clearly, and enhancing mechanisms to communicate these to key stakeholders (also see paragraph 2.32).

## Broader blood sector governance arrangements

**2.13** The NBA operates within a multi-jurisdictional governance and reporting hierarchy (see previous Figure 2.2), in which the Australian Health Ministers' Conference (AHMC) has overarching responsibility and oversight of the Australian blood sector, including setting the governance, policy and financial frameworks under which the NBA operates.<sup>46</sup>

**2.14** The ANAO examined the oversight arrangements, and how the NBA managed the blood supply and broader blood sector matters within this governance structure.

### Oversight of the NBA

**2.15** Much of AHMC's oversight role for blood-related matters has been delegated to the Australian Health Ministers' Advisory Council (AHMAC) and (more recently) the Clinical, Technical and Ethical Principal Committee (CTEPC). The AHMAC considers blood sector matters referred to it by the CTEPC and its sub-committee, the Jurisdictional Blood Committee (JBC).<sup>47</sup>

**2.16** The JBC is the main conduit for blood related high-level policy advice and strategy provided to AHMAC and AHMC, and has a significant role in the operational oversight of the NBA's management of the blood supply. This includes participating in national supply planning and budgeting, and exchanging information with the NBA. The NBA regularly reports its progress in blood supply planning and management to the JBC, and in its secretariat role assists the JBC in progressing a variety of policy issues and blood sector

<sup>46</sup> *National Blood Authority Annual Report 2007–08*, p. 33.

<sup>47</sup> JBC Agenda Paper 2.1, 26 February 2010. In September 2006, the JBC became a sub-committee of CTEPC, which has eight sub-committees.

reforms. Once endorsed by the JBC, policy and operational documents (for example, the annual supply plan) are progressed to AHMAC (usually through CTEPC) before final approval is sought from AHMC.

**2.17** The multiple layers involved in the consideration and clearance of key documents is a mechanism for managing risk and ensuring consensus decisions by the jurisdictions, but it also adds to the complexity of the NBA's administrative environment, and can contribute to delays in progressing blood related issues.

### **Clarity of roles and responsibilities**

**2.18** The complexity of the governance arrangements for the blood sector calls for careful designation of roles and responsibilities between the various entities. Although the National Blood Agreement defines roles and responsibilities for the jurisdictions, the AHMC and the NBA, reviews of the blood sector in 2005 and 2009 identified a lack of clarity in roles—including duplication of effort, significant gaps and lack of clarity in the blood sector governance structure.

**2.19** Unclear roles and responsibilities can increase the risk that particular areas of business will be inadvertently overlooked or delayed. For the NBA to operate more effectively within the existing broader governance structure, clear definition of each entity's specific roles and responsibilities is required.<sup>48</sup> Given that the National Blood Agreement was signed in late 2002, and that various reviews have driven changes to blood sector governance arrangements since then, the development of an up-to-date document, by the parties, outlining the currently agreed division of roles and responsibilities would be useful.

## **The NBA's role in managing blood sector reforms**

**2.20** Since the creation of the NBA, several reviews have been undertaken (see Appendix 4). Collectively, these have provided an extensive examination of many components of the blood sector, especially the ARCBS. The reviews highlighted several areas where management of the nation's blood supply needed improvement, prompting remedial action by governments and key providers of blood products and services.

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<sup>48</sup> The responsibilities of each committee have been examined through external review.

## The administrative review of the blood sector

2.21 The most recent review, completed in late 2009, examined administrative arrangements in the blood sector.<sup>49</sup> The review identified improvements to the blood sector that had occurred since the NBA’s inception in 2003 and areas still to be addressed (Table 2.2).

**Table 2.2**

### Findings of the 2009 Administrative Review

Improvements to the blood sector since NBA’s inception in 2003	Areas still to be addressed
<ul style="list-style-type: none"> <li>• Secure and timely supply on a national basis.</li> <li>• Increased national efficiency, driven by best practice.</li> <li>• More competitive prices for blood products.</li> <li>• Increased product range.</li> <li>• Strengthened risk management, including through the National Blood Supply Contingency Plan.</li> <li>• Creation of a range of guidelines using best practice evidence to support product use.</li> <li>• Reduction in distribution costs and infrastructure.</li> </ul>	<ul style="list-style-type: none"> <li>• Policy and decision making gaps and processes.</li> <li>• The need for simpler, clearer, more focused structures, roles and responsibilities.</li> <li>• Unproductive and inefficient processes in policy, decision making, clearance and implementation.</li> <li>• Lack of communication with and input from stakeholders external to the National Blood Agreement.</li> <li>• Inefficient national supply planning and budget processes.</li> <li>• Inadequate arrangements for listing new products.</li> <li>• Financial sustainability issues, cost-effectiveness and cost containment in regards to appropriate use and wastage.<sup>50</sup></li> </ul>

Source: Report of the *Administrative Review of the National Blood Arrangements*, December 2009.

Note: Inclusion of the above table does not confer agreement by ANAO with the content shown.

2.22 The review emphasised the complex, time consuming and sometimes ambiguous nature of the multi-jurisdictional decision making and governance environment in which the National Blood Agreement operates. A draft implementation plan for recommendations emanating from the review was submitted to AHMC (though CTEPC and AHMAC) for approval in February 2010, but, at that point, CTEPC sought further clarification.<sup>51</sup> The plan was subsequently approved by AHMC in November 2010. Aspects of the NBA’s

<sup>49</sup> This was an Administrative Review of the blood sector (and the National Blood Agreement) required under Clause 37 of the Agreement and undertaken in 2009.

<sup>50</sup> *Administrative Review of the National Blood Arrangements*, 2009, p. 4.

<sup>51</sup> Department of Health and Ageing response to ANAO Issues Papers, December 2010.

external governance arrangements and related responsibilities are subject to revision pending full execution of the plan.<sup>52</sup>

## Managing change

**2.23** Considerable work is being undertaken by the NBA, Australian governments and the ARCS/ARCBS to implement changes recommended in recent reviews, and this was taken into consideration in the audit. The change program generated through the various reviews has been substantial and demanding on the NBA as well as the ARCBS, Australia's provider of fresh blood products and services. In this situation, setting priorities based on an analysis of key risks, costs and benefits and key stakeholder consultation is essential. Equally important is the ability of governance arrangements to provide prompt and informed decision making, so that blood sector reforms can proceed with whole of government and blood sector commitment.

**2.24** A theme in the 2009 Administrative Review was the need to address inefficient decision making processes. Based on ANAO analysis, resolution of significant blood sector issues was not always timely.<sup>53</sup>

**2.25** Table 2.3 presents examples of key issues which progressed slowly or were not resolved. The cause of such delays was not always visible through the NBA's planning documents, policy papers and key governing committee records. However, reasons for slow progress raised or observed during the audit included: the several 'layers' of governing committees; difficulty often encountered in governments reaching a consensus decision (a requirement of the National Blood Agreement); and a lack of clear process in some instances.

**2.26** Specific issues were, at times, referred to the JBC (or higher committees) several times, often due to the multiple phases of development for a proposal, further research being requested or a decision not being reached. The large volume and diversity of work passing through the committees, and the resulting competing priorities, also contributed to delays in resolution of NBA items.

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<sup>52</sup> In relation to the *Administrative Review of National Blood Arrangements 2009*, the ANAO notes that the draft Minutes of the 1 September 2011 meeting of CTEPC noted that 'progress with the implementation plan is largely complete and remaining items will be tracked through quarterly reporting from the JBC.'

<sup>53</sup> ANAO analysis from JBC Minutes and agenda papers. Resolution was by either JBC, CTEPC, AHMAC, or AHMC.

## Table 2.3

### Examples: the progress of blood sector issues

#### Example 1: Output-based funding model

The 2001 Stephen Review recommended that funding arrangements with blood service providers should be output-based. Requirement for an Output Based Funding Model (OBFM) was incorporated into the NBA–ARCS 2006–09 Deed of Agreement, for implementation over the term of that Agreement. A Business Study of the ARCBS in 2008 proposed models for an OBFM. The JBC agreed to principles and a model in July 2010. The ARCBS agreed to introduce the model in July 2010. Although the principles and model had not been approved by AHMC, the NBA advised that the OBFM would be in place for a year, with an evaluation to be conducted and a final model presented to AHMC for approval in July 2011. The OBFM was implemented prior to the blood sector having the information management and data capabilities to monitor ordering, receipt and verification to inform the model.

#### Example 2: Data capacity for efficient and secure supply and appropriate use of blood products

The issue of lack of data capacity was initially raised in the Stephen Review in 2001. There was little activity in this area until 2006, at which point the NBA commenced several initiatives to improve blood sector data capacity including: a data workshop to establish core data priorities (October 2006); tracking the amounts of products received and dispensed to patients; and a bleeding disorder registry. In 2008, the NBA developed a Sector Information Management and Data Strategy (SIMDS). The NBA is currently developing and implementing the various systems of the SIMDS, particularly an ordering, receipt and verification system for blood and blood products.

#### Example 3: Stewardship

The issue of stewardship was incorporated into the NBA–ARCS 2006–09 Deed of Agreement, for implementation over the term of that Agreement. By September 2010, stewardship had not progressed significantly, and the NBA reported that this issue would be included in the negotiations towards the new Deed of Agreement. The NBA drafted a Stewardship Statement, which was endorsed by JBC in May 2010, AHMC in November 2010, and then presented to CTEPC's inaugural Blood Policy Forum in March 2011 for discussion of opportunities to integrate the stewardship expectations at various levels of the blood sector. Forum participants identified challenges to effectively implementing the statement. Further work is planned in 2011 for JBC and CTEPC to progress this initiative.

#### Example 4: Distribution review

A suggested activity from the 2006 Review of Australia's Plasma Fractionation Arrangements was that the NBA review distribution arrangements for blood products.<sup>54</sup> In February 2008, the JBC approved Terms of Reference for the Distribution Review. The review was undertaken (at a cost in excess of \$750 000) in three stages. In December 2010, the JBC noted from the final stage 3 report that 'realisable benefits of implementation of the manufacturer direct distribution model for all plasma and recombinant products are currently not clear and potentially outweighed by the implementation risks.' The JBC therefore recommended that 'NBA commence a supply chain improvement program for plasma and recombinant products.'

Source: ANAO analysis from various NBA documents, including JBC papers.

**2.27** While acknowledging that resolution of timeliness issues may require closer consultation with DoHA and the requisite committees, greater consistency and clearer documentation of procedures would contribute to improving administrative efficiency for the NBA and other government parties. It is important that the NBA continues to examine its processes and evaluate past experiences so that the lessons learned inform program and administrative improvement. Regularly consulting with a wider range of

<sup>54</sup> *Review of Australia's Plasma Fractionation Arrangements* (the Flood Review), 2006, pp. 208–209.

stakeholders is central to this process, as it affords feedback on the external effects that NBA's processes, broader health priorities and blood sector changes, can ultimately have at the client interface.

## Communicating longer-term blood sector priorities and strategies

**2.28** An important consideration in agency planning is the development and communication of short-term, medium and longer-term goals, strategies and milestones.

**2.29** Strategic planning is a process by which an agency decides on approaches to reach its longer-term goals. Importantly, strategic planning is not restricted to organisational boundaries—a strategic approach requires an agency to align itself with its operating environment in order to make informed decisions about the best options to meet agreed outcomes.

**2.30** While strategic planning should be tailored to suit an agency's particular circumstances, central elements typically involve: clarifying the agency's roles and functions; examining its external environment, including current and emerging risks; identifying planned outcomes and signaling priorities to stakeholders; developing implementation strategies along with the resources required to deliver them; and putting in place a performance information framework to monitor progress.

**2.31** Many of the activities required for strategic or longer-term blood sector planning and uptake of reforms depend on the engagement of groups across the different levels of the blood sector. Such engagement can be in terms of:

- seeking input into the planning and development of national strategies to improve the blood sector;
- encouraging participation and ownership of national strategies and priorities;
- coordinating national effort to align with, and support, priority areas; and
- assessing the progress of blood sector efficiency or effectiveness measures.

**2.32** Through these types of engagements, the relationship between an agency and its key stakeholders can make an important contribution to effective administration. It is beneficial to build strong stakeholder



relationships as early as possible using a range of well targeted communication strategies, consistent messages and documented change management plans.

**2.33** The NBA has used a variety of communication mechanisms to inform and engage its stakeholders. In particular, it has: engaged appropriate experts and reference groups in the development of guidelines and policy proposals; shown sound coordination in its management of committees and tenders; and implemented useful reporting through its Annual Report, website, General Manager reports and various situation reports. There were also improvements over the years in the establishment of supplier forums and planning forums.

**2.34** Notwithstanding these activities, the NBA's approach to developing and conveying its strategic priorities, within the context of the governments' policy principles and priorities, was limited. NBA records and ANAO stakeholder consultations indicated that further strengthening of the NBA's communication strategies would be beneficial. External stakeholders considered that the NBA's planning could be more visible, allowing more effective planning of resources by key blood sector entities.

**2.35** The NBA would benefit from a more structured approach to eliciting external stakeholder issues, and providing the public and stakeholders with additional information about the NBA's future directions and longer-term planned activities. This would assist stakeholders to plan and coordinate their own efforts towards more mutual benefits for the blood sector. Useful developments in this area could include a more encompassing communication strategy, including methods to engage a wider cross-section of stakeholders and to gauge the impact of blood sector reforms.

## Recommendation No.1

**2.36** To assist key stakeholders in planning and coordinating their own efforts towards more mutual benefits for the blood sector, the ANAO recommends that the National Blood Authority (NBA):

- within the context of governments' policy objectives, clearly define its longer-term priorities and strategic directions; and
- build upon its existing range of communication activities to make its longer-term priorities and strategic directions more visible to key blood sector stakeholders.

NBA response: *Agreed*

## 3. Coordinating the Blood Supply

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*This chapter considers the performance of the National Blood Authority in coordinating the national blood supply, including measures to improve the cost-effectiveness of blood product purchase and appropriate usage.*

### A national approach to Australia's blood supply

**3.1** A key focus of the National Blood Authority (NBA) is to ensure that all Australian states and territories have a sufficient supply of blood products and services to meet the clinical needs of their respective communities. To achieve this, the NBA undertakes a range of activities relating to the planning and funding of the national blood supply, including entering into and managing contracts with blood product and service providers.<sup>55</sup>

**3.2** The provision of blood products and services, like all government programs, is subject to the principles of efficiency, effectiveness and accountability, with expenditure expected to demonstrate value for money and progress against program outcomes. These principles apply regardless of the source of the blood products—commercial or not-for-profit providers, domestic or overseas.

### Planning for the blood supply

**3.3** Planning for the purchase of blood products is complex. The planning process is subject to agreed national policies and processes, and takes place within a context of diverse state and territory blood sector arrangements, a competitive commercial pharmaceutical sector, and emerging international trends. While the primary policy objectives for the blood sector 'to provide an adequate, safe, secure and affordable supply...' and 'promote safe, high quality management and use of blood products...' <sup>56</sup> are major drivers of blood supply planning, the NBA's annual and longer-term planning strategies also need to be cognisant of secondary policy objectives. These include:

- maintaining reliance on voluntary, non-remunerated donations of whole blood and plasma;

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<sup>55</sup> op. cit., NBA Act, section 4; National Blood Agreement, section 25 (c), (d) and (e).

<sup>56</sup> National Blood Agreement, section 1, p. 2.

- promoting national self-sufficiency;
- making the best use of available resources, and to give financial and performance accountability for the use of resources by all entities involved in the blood sector; and
- maintaining flexibility and the capacity to respond in a timely manner to changing circumstances and needs.<sup>57</sup>

**3.4** The NBA is also required to ‘establish and manage contingency and risk mitigation measures in relation to the national blood supply...’<sup>58</sup> The identification of significant risks is of particular importance in developing supply plans and strategies that contain reliable and cost-effective options to respond to incidents of increased demand for blood product, insufficient supply, new products and changing clinical use.

### **Affordability and efficiency of the blood supply**

**3.5** One of the reasons for establishing the NBA was to enable central purchasing of blood products and services, to assist in managing costs and ensuring affordability into the future. A national approach also offered opportunities to improve the capability of governments to monitor the cost of blood products, gain insight into supply and product wastage issues, and promote best practice in the use of blood products in a nationally consistent way. National commitment to activities in these areas is an important factor in achieving longer term effectiveness and efficiency of the blood sector.

**3.6** In consideration of this environment, and the NBA’s legal and policy obligations, the ANAO examined the NBA’s approach to coordinating the national supply of blood and blood products to ensure a sufficient and effective supply. The examination focused on:

- funding of blood products and services;
- monitoring the cost of Australia’s blood supply; and
- the link between cost, safety and appropriate use of blood products.

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<sup>57</sup> Ibid., p. 2.

<sup>58</sup> op. cit., NBA Act, section 8; and National Blood Agreement, section 25.

## Funding of blood products and services

3.7 The National Blood Agreement defines the funding of the national blood supply as a joint arrangement between the Australian Government (which contributes 63 per cent of total funds) and the states and territories (which provide 37 per cent of total funds).<sup>59</sup>

3.8 Funds are managed through the *National Blood Account*, a special account specified under the NBA Act, with the majority expended on NBA-managed contracts for blood products and services provided to the states and territories.<sup>60</sup> Since its establishment in 2003, the NBA has negotiated contracts with 10 suppliers of blood products and services. The two largest contracts (Australian Red Cross Society and CSL Limited) represent about 75 per cent of total expenditure (Table 3.1).

**Table 3.1**

### The NBA's main contract categories

#### **Fresh blood products—the Deed of Agreement with the Australian Red Cross Society (ARCS)**

- The ARCS (through the Australian Red Cross Blood Service—ARCBS) is the only supplier of fresh blood components to Australia. Over the period of 2006–11, under the ARCS–NBA Deed of Agreement, the Australian governments provided \$2.3 billion to the ARCBS to 'collect, manufacture and distribute fresh blood products from voluntary donations, and distribute plasma products and imported blood products to hospitals and other users in Australia.'<sup>61</sup>

#### **Domestic plasma-derived products—a commercial contract with CSL Ltd.**

- The NBA has contractual arrangements with CSL to provide an estimated \$2.4 billion over the period 2010–17 for the supply of most of Australia's plasma-derived products. The ARCBS provides plasma from Australian blood donations to CSL to manufacture these products.

#### **Imported blood products— other commercial contracts with products providers**

- In 2009–10 the NBA spent \$215 million on imported blood products to supplement the domestic supply.<sup>62</sup> There were 14 different contracts for supply, with varying duration and cost. Chapter 5 examines an example of such a contractual arrangement.

Source: ANAO, compiled from <[www.nba.gov.au/compliance/pdf/murray-motion.pdf](http://www.nba.gov.au/compliance/pdf/murray-motion.pdf)> [accessed 26 July 2011]; and NBA Annual Reports.

Note: The NBA's contract management for fresh blood products and blood services through the ARCBS and a commercial product provider, Baxter Healthcare Pty. Ltd. (Baxter), are dealt with in Chapters 4 and 5 respectively. The audit did not examine CSL or other commercial contracts.

<sup>59</sup> op. cit., National Blood Agreement, pp. 24–26.

<sup>60</sup> Funding for the supply of blood and blood products, and the operation of the NBA, is managed through the *National Blood Account*, established under section 40 of the NBA Act.

<sup>61</sup> <[www.nba.gov.au/pubs/facsheets](http://www.nba.gov.au/pubs/facsheets)> New NBA and ARCS Deed of Agreement [accessed 19 August 2009]; and NBA information 2011.

<sup>62</sup> op. cit., NBA Annual Report 2009–10, pp. 57–58.

**3.9** These contracting activities have allowed the NBA to operate as a central purchaser of blood products and services, negotiating national prices on behalf of the Australian, state and territory governments. Prior to the advent of the NBA, the state and territories had to negotiate product prices individually.

**3.10** The budget for the purchase of blood products is determined through an annual planning process in which the states and territories are required to estimate their requirements for the coming financial year.

### **National Supply Plan and Budget**

**3.11** The NBA coordinates and submits a National Supply Plan and Budget (NSPB) for blood and blood products, including a National Product Price List, to the Australian Health Ministers' Conference (AHMC) each year for approval.<sup>63</sup> The NSPB specifies the amount and range of products that the NBA will purchase to meet Australia's needs over the coming 12 months, and the funds that the NBA will require to purchase these products and services.

**3.12** Schedule 2 of the National Blood Agreement specifies the key steps for the annual planning and budgeting framework: demand and supply information gathering; formulation of annual plans by the NBA; and approval of annual plans by the Jurisdictional Blood Committee (JBC) and AHMC.

**3.13** Consistent with this framework, the NBA has established processes that base the NSPB on: demand estimates provided by jurisdictions; NBA demand trend analysis; and product prices in supply contracts negotiated by the NBA with suppliers. It also has post-implementation procedures in place, which included: continuous monitoring of demand and supply against the approved NSPB; a mid-year review of the supply plan and funding; and monthly reporting to the JBC.

#### *Monitoring demand and expenditure against the NSPB*

**3.14** The NBA conducts a mid-year review of the NSPB to check that the actual demand and cost of blood products is tracking well against the predicted demand and appropriated funds. Figure 3.1 and Table 3.2 show the

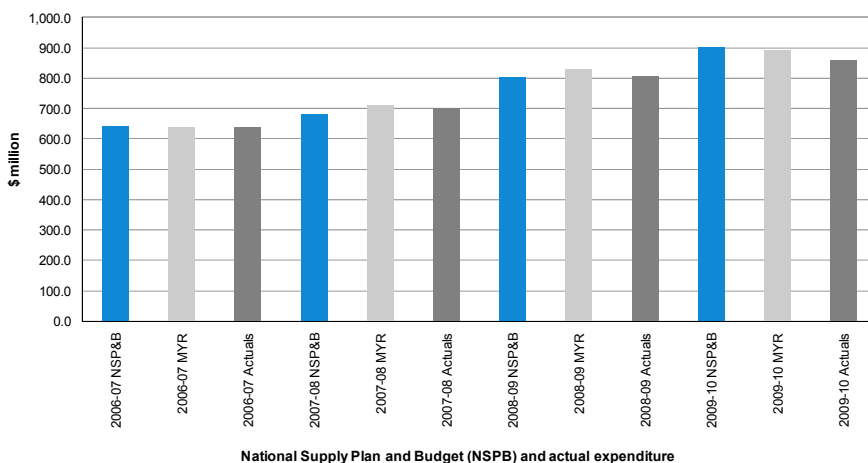
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<sup>63</sup> op. cit., NBA Act section 8 (c). The NBA Act requires the NBA to 'carry out national blood arrangements relating to annual plans and budgets for the production and supply of blood products and services'. The process by which this should be done is provided in schedule 2 of the National Blood Agreement.

variation between the NSPB estimates, mid-year review and actual blood product costs, and demonstrate the NBA’s track record for anticipating and meeting annual demand.<sup>64</sup>

**Figure 3.1**

**Planned, mid-year review and actual costs for 2006–07 to 2009–10**



Source: NBA Annual Report 2009–10, p. 35.

Note: Abbreviations used are: MYR (Mid-Year Review); and NSPB (National Supply Plan and Budget).

**3.15** There was reasonable alignment between the estimated budget and actual expenditure/demand given that the blood supply is largely demand driven.

<sup>64</sup> Total demand for blood and blood products is within the defined 5 per cent variance of total demand predictions by the NBA. This is an output measure in the NBA’s 2010–11 Portfolio Budget Statement, p. 700.

**Table 3.2****Planned, mid-year review and actual costs for selected blood products**

Blood Product Category	2008–09				2009–10			
	NSPB (\$)	Mid year review (\$)	Actual issued (\$)	Difference in Actual to NSPB	NSPB (\$)	Mid year review (\$)	Actual issued (\$)	Difference in Actual to NSPB
Albumin	15 202 965	14 862 753	14 809 333	393 632	17 388 722	18 764 547	21 016 317	3 627 596
Total IVIg	159 213 886	157 627 222	155 682 634	3 531 252	181 477 122	178 160 752	176 231 651	5 245 470
Total Factor VIII	106 340 959	112 901 071	104 155 865	2 185 094	127 685 216	115 908 393	112 166 553	15 518 663
Total Factor IX	22 638 609	27 636 278	26 064 039	3 425 430	30 386 706	29 243 291	27 748 264	2 638 442
Factor VIIa	17 770 894	20 613 661	17 403 879	367 015	20 791 860	27 407 405	26 426 436	5 634 576
FEIBA	10 222 500	17 472 500	13 476 300	3 253 800	15 129 400	19 220 629	14 498 550	630 850
<b>Total</b>	<b>331 389 813</b>	<b>351 113 485</b>	<b>331 592 049</b>	<b>202 236</b>	<b>392 859 026</b>	<b>388 705 017</b>	<b>378 087 772</b>	<b>14 771 254</b>

Source: NBA Annual Report 2008–09, p. 33; and data provided by the NBA.

Note: Abbreviations used are NSPB (National Supply Plan and Budget); FEIBA (Factor Eight Inhibitor Bypass Agent).

***Monitoring demand and expenditure against the NSPB***

**3.16** Key Performance Indicators (KPIs) under the contractual arrangements between the NBA and the Australian Red Cross Blood Service (ARCBS) are also used to demonstrate whether supply requirements for fresh blood products (including plasma collected by the ARCBS for fractionation by CSL) are met. Table 3.3 illustrates annual performance against the supply targets, as reported by the ARCBS.<sup>65</sup>

<sup>65</sup> Figures reported by the ARCBS in its 2008–09 and 2009–10 Annual Reports.

**Table 3.3****Percentage of the Supply Plan met by the ARCBS**

Key Performance Indicator	Target 2008–09	Actual 2008–09	Target 2009–10	Actual 2009–10
Per cent red cell supply met	100	99	100	98
Red cell supply figure (units)	798 322	793 480	811 377	795 892
Per cent total platelet supply met	100	100	100	106
Total platelet supply figures (equivalent adult doses)	118 795	118 248	121 575	128 495
Per cent apheresis platelet supply met	100	96	100	91
Apheresis platelet supply figures	47 177	45 415	[54 256] 53 746	48 767
Per cent clinical FFP supply met	100	101	100	105
Clinical FFP supply figures	[153 545] 151 659	152 689	153 335	160 813
Per cent CSL Ltd plasma supply met	100	103	100	100
CSL Ltd supply figure (kg)	380 500	390 707	451 000	452 422
Per cent Actual Cost to budget performance	100	99	100	98

Source: Australian Red Cross Blood Service Annual Reports 2008–09 and 2009–10.

Note: These figures were provided by the ARCBS and verified by the NBA. Blue entries indicate where NBA figures differ from those supplied by the ARCBS.

## The cost of Australia's blood supply

**3.17** The NBA's national supply arrangements aim to provide Australians with access to a secure supply of blood products within a reasonable budget (that is, the supply has to be affordable).<sup>66</sup> Meeting this challenge involves balancing national blood policies and budget imperatives against the growing demand for blood products (which is influenced by factors such as growth and ageing of the population, introduction of new products and safety measures, and new indications for blood products).

**3.18** While national policy objectives recognise that Australia's blood supply needs to be 'affordable'<sup>67</sup>, Australia's blood supply costs have been steadily

<sup>66</sup> NBA Annual Report 2009–10, p. 28; and *Health and Ageing Portfolio Budget Statements 2009–10*, p. 617.

<sup>67</sup> op. cit., National Blood Agreement, pp. 1–2.



rising.<sup>68</sup> Over the period of 2003–04 to 2009–10, the NBA’s total blood expenditure rose by an average of 11.4 per cent per annum.

**3.19** The ANAO examined how the NBA was monitoring blood product and service costs, and the steps being taken to further the goal of affordability—including strategies to contain expenditure. In this context, the ANAO examined the NBA’s approach to:

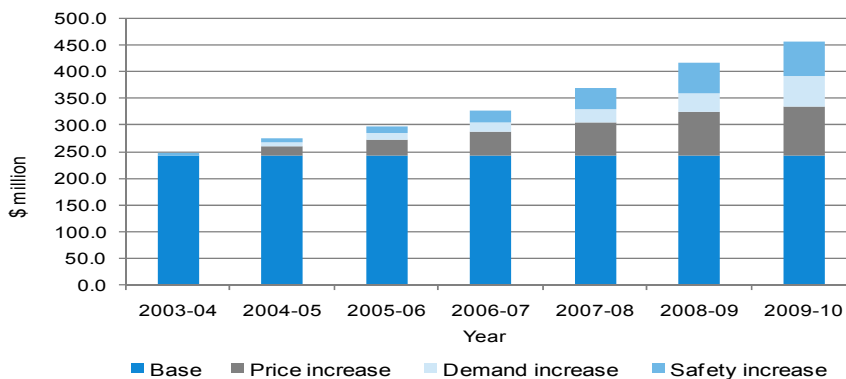
- monitoring national expenditure on fresh blood products; and
- providing a sufficient supply of plasma and imported blood products.

### Monitoring national expenditure on fresh blood products

**3.20** The NBA monitors fresh blood product and service expenditure to the individual products level, and by state and territory. The consolidated national trend in fresh blood expenditure is reported in the NBA’s 2009–10 Annual Report (Figure 3.2).<sup>69</sup> Over the seven-year period to 2009–10, funding for fresh blood products and services grew from \$243 million to \$456 million per annum.

**Figure 3.2**

#### Fresh blood expenditure 2003–04 to 2009–10



Source: NBA Annual Reports and data provided by the NBA.<sup>70</sup>

Note: As no pre-2003–04 data was provided, the relative impact of safety and specific product demand prior to this date is not evident.

<sup>68</sup> See Chapter 2, Figure 2.1.

<sup>69</sup> op. cit., NBA Annual Report 2009–10, p.36.

<sup>70</sup> The base line for the analysis is 2002–03 costs, coinciding with the establishment of the NBA.

**3.21** As shown above, the NBA attributes increases in expenditure for fresh blood products and services to a combination of price, demand and safety measure costs. The average per annum cost increase for each of these elements is also given in Table 3.4.

**Table 3.4**

**Breakdown of fresh blood expenditure increases**

Cause of cost increase	Cost increase for 2009–10 (\$ million)	Average per cent increase per annum 2003–04 to 2009–10
Price increases	\$91	7.5
Demand increase for fresh products, principally red cells, platelets, and blood for fractionation	\$58	4.7
Safety measures approved by government, including leucodepletion <sup>71</sup> of red cells and platelets and bacterial testing for platelets	\$64	5.2

Source: NBA, Annual Report, 2009–10, p. 35.

**3.22** The NBA attributes the greatest proportion of increases (\$91 million) to in ‘price increases’, although<sup>72</sup> it does not make clear the full basis of this amount. For example, any flow-on of safety measure costs to end product price, or future savings (including in the broader health sector) expected as a result of the additional safety measures, are unclear. The NBA’s reporting of safety costs (\$64 million) would be enhanced by comparison with, for example, pre-NBA blood supply costs.<sup>73</sup>

**3.23** The NBA has stated that it ‘has limited opportunity to influence the cost of fresh blood components’.<sup>74</sup> The cost to governments for fresh blood products is ascribed through a single contract between the NBA and the ARCS (see Table 3.1 and Chapter 4)—a contract amounting to \$2.3 billion expenditure over the period 2006–11. As a matter of government policy and current practicality, there are no other providers of fresh blood services in Australia; a situation that has prevailed for some 80 years.

<sup>71</sup> Leucodepletion is the process of removing white blood cells from blood, a process which improves the safety of the blood product.

<sup>72</sup> op. cit., NBA Annual Report 2009–10, p. 35. Also see NBA Annual Report 2008–09, p. 31.

<sup>73</sup> NBA stated that earlier data was not available because each state had separate contracts and a different mix of safety measures prior to NBA’s establishment.

<sup>74</sup> op. cit., NBA Annual Report 2008–09 p. 31.

**3.24** In this type of established monopoly, value for money cannot be assessed through the usual evaluation of competitive tenders. Instead, important considerations include: the extent of the ARCBS's organisational efficiency; its contractual performance; and its capacity to provide affordable blood products and services to the standards required over time.<sup>75</sup> Value for money can also be realised through the effectiveness of the NBA's management of the ARCBS contract (also see Chapter 4), including its ability to influence improvements to fresh blood services and product quality, and the extent to which agreed standards and performance targets are met.

**3.25** It was evident that the NBA and ARCBS had invested considerable time and resources in reviewing the efficiency of the blood sector and implementing activities to improve many areas of ARCBS business. Specific examples include: implementation of the 35 recommendations from a business study, aimed to improve the business efficiency of the ARCBS (this includes an output-based funding model for fresh blood products); development of a national system for ordering and receipting of blood; and various guidelines for health professionals. To date, the NBA has had limited ways of measuring the cost-effectiveness of these measures.

**3.26** To allow proper assessment and insight into the impact (including cost-effectiveness) of such blood sector efficiency measures in the medium to long term, the NBA and ARCBS will require a greater focus on establishing suitable standards for contract deliverables and performance, and improving data systems to capture sufficient information on blood product use and wastage.

**3.27** Improved standards and systems will support the NBA in the development of longer-term strategies and mechanisms for determining value for money for the blood supply (these matters are also discussed later in this chapter). Similarly, a clearer indication of the expected benefits of the safety measures, and the impact of these over time, would assist the NBA in demonstrating medium to longer-term value for money. Understandably, the development of appropriate evaluation strategies is necessary to achieve this (also see Chapter 6).

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<sup>75</sup> Also refer to Chapter 4, which examines the Deed of Agreement between the NBA and ARCS/ARCBS.

## Funding of plasma-derived and imported blood products

**3.28** Plasma-derived products include albumin, immunoglobulins and other protein products, which are fractionated (separated) from plasma and used in the treatment of particular bleeding disorders and immune deficiencies. Imported products include a range of plasma-derived blood components, as well as synthetic (recombinant) blood products such as Factors VIII and IX clotting factors (also see Appendix 2).

**3.29** The policies and contractual circumstances for plasma-derived and imported products are different to that of fresh blood (see Table 3.1 and paragraph 3.23).<sup>76</sup> A review of the plasma fractionation services in Australia, undertaken in 2006, led to a government policy that the processing of Australian blood for plasma products would remain in Australia.<sup>77</sup> The AHMC has also clarified the position of governments on the self-sufficiency of the blood supply, indicating scope to import plasma-derived and recombinant products:

...Importation of blood products does occur in a narrow range of circumstances where there is an inability to meet clinical needs through the domestic supply, and where supply chain risks must be addressed...Australia is self-sufficient in fresh blood components/products except for a few rare blood types, and is largely self-sufficient in plasma products. However, it is necessary to import products such as Intravenous Immunoglobulin (IVIg) where demand exceeds what is produced domestically and recombinant products, which are not produced in Australia...<sup>78</sup>

**3.30** Annual supply planning for plasma-derived and imported products takes this policy position into consideration, with each year's proposed supply plan and budget containing options for the JBC to consider regarding the amount of imported Intravenous Immunoglobulin (IVIg) and other products to be purchased. These options are based on state and territory demand estimates and product trend analysis, as well as supply contingency and cost considerations.

**3.31** There is scope for commercial competition to offer value for money for imported products. This is most evident at the individual contract level, where prices can be negotiated with potential product providers. Notwithstanding

<sup>76</sup> Fresh blood products are provided under a single-provider contract with the ARCS. Imported plasma-derived products and recombinant products may involve multiple suppliers and competitive tendering.

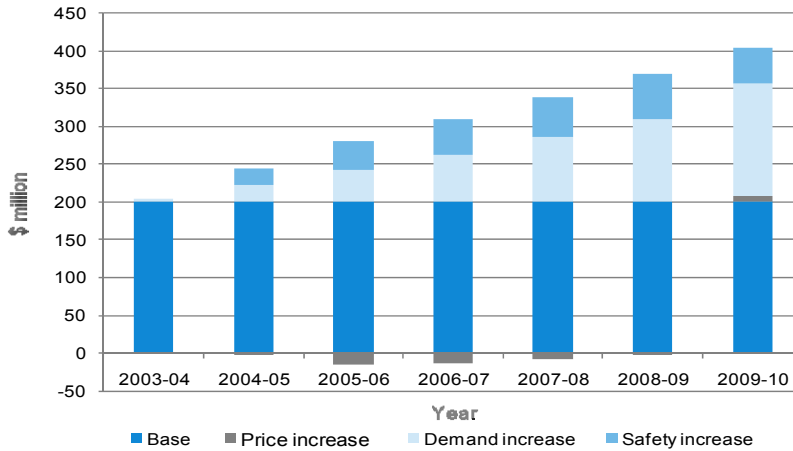
<sup>77</sup> The *Review of Australia's Plasma Fractionation Arrangements* (the Flood Review), 2006; and media release, Tony Abbott MHR, Plasma fractionation arrangements, 30 March 2007.

<sup>78</sup> *AHMC Policy Statement on National Self-Sufficiency in the Supply of Blood and Blood Products*, AHMC meeting 7 April 2006.

this, collectively, there has been significant growth in the NBA's expenditure for plasma and imported products over the last six years (Figure 3.3).

**Figure 3.3**

**Plasma-derived and imported product expenditure 2003–04 to 2009–10**



Source: NBA Annual Reports and data provided by the NBA.

**3.32** The NBA attributes this growth in expenditure primarily to:

- increased demand for intravenous immunoglobulin and some clotting factors; and
- safety increases through replacement of plasma-based clotting factors by the recombinant products.<sup>79</sup>

**3.33** The ANAO examined the NBA's implementation of government policy on IVIg supply and how the NBA was more generally managing the rising demand and expenditure for IVIg.

*National supply of Intravenous Immunoglobulin (IVIg)*

**3.34** Achieving an adequate supply of IVIg has been a significant issue for the NBA to manage. Since the early 1990s Australia has been aware of shortfalls in meeting rising patient demand for IVIg through domestic production. In 2003–2004, such shortfalls led to a decision by Australian governments to allow the importation of a contingency supply of IVIg, under standing offer arrangements, to supplement domestic supply. The importation

<sup>79</sup> op. cit., NBA Annual Report 2008–09, p. 30; and 2009–10, p. 39.

of products was effected through the NBA’s tendering and contracting processes.<sup>80</sup>

**3.35** The following data show that since 2004 Australia’s use of IVIg has doubled and the proportion of imported IVIg to total IVIg has gradually increased. Imported IVIg reached 27.7 per cent in 2008–09. The planned amount for importation in 2010–11 is 17.2 per cent.<sup>81</sup>

**Table 3.5**

**Example: Domestic and imported Intravenous Immunoglobulin**

Ratio of domestic to imported Intravenous Immunoglobulin (IVIg) supply									
IVIg (Kg)	02–03	03–04	04–05	05–06	06–07	07–08	08–09	09–10	10–11
Domestic	1148.50	1341.60	1353.12	1359.12	1567.19	1758.14	1717.87	2022.24	2422.45
Imported	0	28.20	81.29	307.78	328.25	387.17	657.16	630.76	502.45
Total	1148.50	1369.80	1434.41	1666.90	1895.44	2145.31	2375.03	2653.00	2924.90
IVIg (%)	02–03	03–04	04–05	05–06	06–07	07–08	08–09	09–10	10–11
Domestic	100	97.9	94.3	81.5	82.7	82.0	72.3	76.2	82.8
Imported	0	2.1	5.7	18.5	17.3	18.0	27.7	23.8	17.2

Rising demand for IVIg has been attributed to a combination of factors, including increases in, and ageing of, the population; and new clinical uses for IVIg. The Government’s position has to date indicated that IVIg importation is a contingency measure.

Source: NBA data derived from ‘BigRed’ data system June 2011; NBA data from National Supply Plan and Budget (2010–11). Figures also provided by the Australian Red Cross Blood Service, April 2010. Other sources of information were various JBC and AHMC meeting records and *Criteria for the clinical use of intravenous immunoglobulin (IVIg) in Australia, 2007*.

Note: There were minor differences between ARCBS and NBA data provided during the audit. With the exception of 2002–03, the above data are NBA sourced. Data could not be verified.

**3.36** The IVIg sourcing issue emphasises the complexity of planning for the national blood supply and the balance that needs to be achieved to meet patient demand as well as government policy in terms of: the adequacy of supply; affordability of supply (which logically includes containing costs); promotion of self sufficiency; and the provision of blood products free of charge to patients.<sup>82</sup>

<sup>80</sup> Australia Health Ministers’ Conference, *Criteria for the clinical use of intravenous immunoglobulin in Australia*, Commonwealth of Australia, December 2007, p. 245; and Stephen Review, 2001, pp. 74–75 and 104.

<sup>81</sup> Australian Red Cross Blood Service data; and NBA advice 23 May 2011.

<sup>82</sup> As indicated through the primary and secondary policy objectives of the National Blood Agreement.

### *Containing IVIg use and cost*

**3.37** IVIg use has increased at around 11 to 13 per cent per annum in recent years, and in 2009–10 IVIg accounted for 20 per cent of the national supply budget.<sup>83</sup> Containing growth and/or securing a greater supply of IVIg are important issues for government and the NBA. Approaches that can reduce use and costs include: obtaining better value for money in purchasing; improving appropriate use of products; and monitoring the issue and use of products to identify opportunities for improvement.

**3.38** Apart from addressing clinical/patient needs the importation of IVIg presents opportunities to reduce Australia's overall expenditure on IVIg through competitive pricing by overseas providers.<sup>84</sup> Conversely, the ongoing nature of the contingency measure to import IVIg demonstrates the tension with national policy on self-sufficiency.<sup>85</sup> Greater clarity of national priorities for the security and affordability of the IVIg supply, as well as national trends in this area, has the potential to support longer-term planning in the blood sector.

**3.39** The introduction of criteria on clinical practice in IVIg use is also an example of action by governments to promote best practice and limit the use of IVIg to those with the greatest need.

Where safe, effective and affordable alternative therapies exist, these are considered preferable to IVIg. When IVIg is used, the lowest dose for the shortest duration required to achieve the desired outcome should be chosen. For ongoing therapy, the achievement of measurable clinical outcomes is a requirement and IVIg should not be continued in patients with no demonstrable clinical benefit.<sup>86</sup>

**3.40** The ARCBS also has a 'gatekeeper' role in authorising and monitoring the appropriate use of IVIg, which assists Australian governments in managing national IVIg supply.

**3.41** The above actions, while having a strong focus on achieving best clinical practice and patient outcomes, are also important for controlling the use of IVIg so that shortfalls are less likely to occur, and can contribute to controlling expenditure for this group of products. Enhancing these activities,

<sup>83</sup> NBA Annual Report, 2009–10, pp.33 and 42.

<sup>84</sup> Principles of the FMA Act and *Commonwealth Procurement Guidelines* (CPGs).

<sup>85</sup> Self-sufficiency is a secondary policy of the National Blood Agreement.

<sup>86</sup> op. cit., *Criteria for the clinical use of intravenous immunoglobulin (IVIg) in Australia*, p. 3.

to give greater insight into IVIg usage patterns, would enable better targeting of appropriate use strategies for IVIg and aid planning for future IVIg supply.

**3.42** A review of the IVIg criteria (currently underway), may be useful in this pursuit, although strengthening the monitoring and authority mechanisms (to approve use of IVIg) may also need to be considered. These latter activities will require specific attention by the NBA in the immediate future, with the assistance of the states and territories and the cooperation of the Approved Health Providers (AHPs) and the ARCBS.

## The link between cost and appropriate use of blood products

**3.43** The NBA's functions focus strongly on the provision of 'sufficient supply of blood and blood products'. In the broader context of national blood sector policy, the blood supply also needs to be affordable and the blood sector accountable for expenditure and product use.<sup>87</sup>

**3.44** Figure 3.2 demonstrates a relationship between the cost of blood products and the introduction of safety measures. There is also a relationship between cost and appropriate use of blood products, the premise being that improving appropriate use, particularly through more informed clinical decisions, will help to reduce expenditure.<sup>88</sup> These factors are important when considering value for money and efficiency in the blood supply, as illustrated below.

Efficiency can be considered in terms of

- the amount of blood collected, and how efficiently this is used. For instance, how much over-collection is occurring or how much product expires before use and is discarded;
- the safety of the products and whether there are additional medical costs in treating adverse events to blood products, or liability costs as a result of viral contamination of the supply; and
- whether the blood and blood products are distributed in the most effective way so there is suitable access to the most appropriate products when needed.

**3.45** Obtaining value for money requires a judgement about the quality of a product or service relative to its cost—a trade-off between cost and quality in which, typically, the higher the quality, the greater the cost. To date, the NBA has been able to exercise value for money practices mainly through its

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<sup>87</sup> op. cit., National Blood Agreement sections 1 (a) and 2 (f).

<sup>88</sup> There can also be legitimate instances where appropriate use strategies result in higher usage of blood products.



commercial contracting activities and unit pricing. The broader and longer-term perspective of value for money, including through appropriate use and minimising wastage, has not yet been measurable due to the lack of data and information available (this is examined further in Chapter 6).

### **Strategies for promoting appropriate use of blood products**

**3.46** Through the NBA Act and the National Blood Agreement, the NBA has a role in promoting strategies for the appropriate use of blood and blood products. The state and territory governments and the ARCBS also have roles in this endeavour. Implementing strategies to promote appropriate use requires communication and collaboration between these parties and Approved Health Providers. Examples of how the NBA is addressing key national policies in this area are set out below (Table 3.6).

**Table 3.6**

**Meeting national policy on appropriate use of blood products**

National policy includes:	Examples of NBA activities to meet these functions:
To provide products to patients free of charge and based on clinical need and appropriate clinical practice.	<ul style="list-style-type: none"> <li>• Products are provided free of charge to patients through current funding mechanisms, in line with national policy, as determined by AHMC and implemented by NBA and the Jurisdictions.</li> <li>• Annual supply plan and budget considers amounts of products required each year, and considers trends in product use and availability of products.</li> <li>• Facilitation and contracting for the development of clinical guidelines and criteria.</li> </ul>
To promote optimal safety and quality in the supply, management and use of products, including through uniform national standards.	<ul style="list-style-type: none"> <li>• Implementation of government policy on access to recombinant products through procurement activities.</li> <li>• Funding of safety measures based on business cases and evidence-based assessment, and implementation of these under the NBA–ARCS contract for fresh blood products and services.</li> <li>• Implementation/promotion of clinical guidelines and appropriate use criteria.</li> <li>• Management of use strategies and guidelines in progress—additional work in monitoring, evaluation of quality measures required.</li> <li>• Involvement in the development of national standards—this has been an area of less activity, with much more to accomplish over the next few years.</li> </ul>
To maintain flexibility and capacity to respond in a timely manner to changing circumstances and needs.	<ul style="list-style-type: none"> <li>• Annual planning activities and mid-year reviews.</li> <li>• Horizon scanning for international trends, new products, technologies and standards.</li> <li>• Contingency plans and activation of these when required.</li> <li>• Strategic risk management framework.</li> <li>• Financial capacity into the future was still a concern given continuing and substantial increases in expenditure. A greater focus on a more strategic cost containment strategy may assist in this area.</li> <li>• Schedule 4 and MCA process to allow introduction of new products.</li> </ul>

Source: Section 2 of the National Blood Agreement, p. 2 and ANAO analysis.

**3.47** The NBA has demonstrated its involvement in many elements of national policy implementation to varying degrees. The agency’s Annual Reports provide a reasonable source of information on achievements to date. Several reviews undertaken since 2003 have also helped to identify areas of the blood sector that required strengthening to achieve further efficiencies, and a significant change agenda is underway.

**3.48** Table 3.7 shows some of the activities underway to improve and inform more appropriate clinical use of blood products within the blood sector. Such strategies can contribute to reducing wastage of blood products or their

inappropriate use, and over time may help to reduce overall costs (for example, through better monitoring and management of products wastage)

**Table 3.7**

**Examples: NBA funded programs and projects to improve clinical management in the blood sector**

Program/project	Progress to date
National Haemovigilance Program	A national Haemovigilance Advisory Committee with representatives from the public, private hospitals, pathology, state governments and the ARCBS meets on a regular basis to raise awareness of the nature and causes of adverse events relating to blood transfusions. Two National Haemovigilance reports have been produced.
NHMRC Patient Blood Management Guidelines	These guidelines have a specific focus on how to reduce the need for blood transfusions and have involved, to date, approximately 60 clinical experts. <sup>89</sup> Six Guidelines are to be produced. Of these, the first was released in February 2011; public consultation is completed on the second guideline; and the remainder are to be completed over the next two years.
Blood Measures	The Blood Measures guide was developed by the NBA and the ARCBS to assist people undertaking investigations of the use of fresh blood components (red blood cells, platelets, fresh frozen plasma and cryoprecipitate). It is designed to be an easy reference guide for clinicians, transfusion practitioners, auditors and researchers. During 2011, the Guide will be finalised to take into account standards developed by the Australian Commission on Safety and Quality in Health Care and definitions from NBA work on data standards and governance.
Education initiatives	The NBA provides support and a national focus to the e-learning system from South Australia and the graduate certificate program from Victoria. These two projects aim to build state based education initiatives into nationally deployable capabilities. The concept is to design nationally consistent entry level training through tertiary level qualifications in all facets of transfusion practice.
Other guidelines	Other guidelines have been produced either by or in collaboration with the NBA since 2003 including: Prophylactic Use of RhD immunoglobulin in obstetrics; and the AHMAC Factor VIII and IX guidelines.

Source: Information provided by NBA, September 2010.

## Strengthening longer-term planning for cost-efficiency

**3.49** The supply of quality blood or blood services to patients in need is a core aim of government and the blood sector. However, the inappropriate use of blood products is a known risk in terms of patient outcomes, as well as to the efficiency and effectiveness of the blood supply. The NBA recognises the need for long-term planning in this area, stating in its 2010–11 Portfolio Budget Statements that it would ‘improve long-term planning, particularly through

<sup>89</sup> NBA update 24 September 2010.

improved data analysis and stakeholder engagement, to facilitate the appropriate use of blood products.'

**3.50** Numerous activities were either underway, in development or planned, to address the NBA's key legislative functions and government policy directions around appropriate use and blood sector efficiency (see examples in Table 3.6). Notwithstanding this, gaps were apparent in a number of areas, including: strategic planning; setting priorities for research and evaluation; data collection and analysis capability; and stakeholder interactions.

**3.51** In addressing some of these gaps, the Department of Health and Ageing (DoHA) funded two projects: Blood Sector Research Gap Analysis; and Impediments to Better Practice Demand Management in the Blood Sector. These were intended to complement current work in investigating the demand and cost trends in the blood sector and possible strategies for the appropriate use of blood, such as price signalling. The projects should also contribute to a broader understanding of the financial sustainability of the Australian blood sector by governments.<sup>90</sup>

**3.52** Sustainability of the blood supply is dependent on a broad range of factors, including building on the donor pool, purchasing and using blood products wisely; and being able to monitor usage trends and foresee emerging needs. The efficiency and quality of services is also influenced by a diversity of stakeholders, many of whom (directly and indirectly) have a role in delivering blood products to patients. In particular, consultation and engagement with Approved Health Providers (AHPs) is pivotal to implementing, monitoring and encouraging appropriate use of blood products, especially in obtaining commitment to national strategies.

**3.53** Given these interdependencies, and an environment where blood product use and government expenditure is markedly rising, there would be value in the NBA (with the help of its governing bodies and key stakeholders) strengthening its planning and priority setting to focus more on the affordability of the blood supply. In particular the various projects and activities should be consolidated under clearer strategic directions, so that the long-term approach to cost-efficiency is apparent. The approach would also

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<sup>90</sup> In June 2011, the NBA advised the ANAO that reports for each of these projects had now been provided to DoHA.

identify appropriate performance measures and the means to collect suitable data to measure the impact of appropriate use strategies on blood sector costs.

## Recommendation No.2

3.54 To support future blood supply affordability, the ANAO recommends that the NBA, in consultation with key stakeholders (including the ARCBS, JBC and DoHA), develop a strategy to encourage cost-efficiency across the blood sector. The strategy should clearly incorporate national priorities, key linkages between national policies and activities, and performance measures against medium and longer-term outcomes.

NBA response: *Agreed*

## 4. The Deed of Agreement between the NBA and the ARCS

*This chapter examines the contractual arrangements between the National Blood Authority (NBA) and the Australian Red Cross Society (ARCS) for the provision of blood products and services through the Australian Red Cross Blood Service (ARCBS).*

### Providing Australians with fresh blood products and services

**4.1** Approximately 50 per cent of the National Blood Authority’s annual blood supply budget is spent on fresh blood products and services. These products and services are provided to all states and territories by the Australian Red Cross Blood Service (ARCBS), under a Deed of Agreement (the Deed) between the NBA and the Australian Red Cross Society (ARCS). In 2009–10, the Australian governments spent \$456 million on fresh blood products and services across Australia under the Deed arrangements.<sup>91</sup>

**Table 4.1**

#### Fresh blood products and services provided by the ARCBS

Products	Services
<p>Fresh blood products include such items as plasma, platelets and red blood cells, which are vital for the clinical support of people with a range of medical conditions and for individuals undergoing surgery.</p> <p>The ARCBS is also responsible for providing starting plasma (derived from voluntary blood donations) to CSL Limited for fractionation into various plasma-derived products.</p>	<p>Fresh blood services include donor recruitment and collection of blood, processing of blood into various products, and the distribution of these to Approved Health Providers (AHPs) for administration to patients.<sup>92</sup></p> <p>Other services include ARCBS advice on the appropriate use of blood products, research and educational needs. Provision of fresh blood products also encompasses the testing of blood donations and monitoring product inventory and wastage at the AHP interface.<sup>93</sup></p>

Source: ANAO.

<sup>91</sup> The Australian governments include the Australian (Federal), state and territory governments. The Australian Government contributes 63 per cent of funding and the states and territories combined providing 37 per cent (also see Chapter 3).

<sup>92</sup> Under the Deed of Agreement, the ARCBS also distributes plasma-derived products and a limited number of recombinant products to AHPs.

<sup>93</sup> With the introduction of an Output Based Funding Model (OBFM) on 1 July 2010, these functions are now considered product costs; previously they were regarded as fresh blood services.

**4.2** As the demand for fresh blood products and services increases, effective management at all levels of the blood sector is necessary to ensure that Approved Health Providers (AHPs) have the products they require to treat patients, while keeping the cost of the blood supply within an affordable range for governments. Of particular importance is the maintenance of an appropriate donor population, as this is the cornerstone of Australia’s fresh blood supply.

**4.3** Fresh blood products have a short shelf-life (Table 4.2). Consequently, the collection of blood from donors for processing, manufacture of products and distribution is a year-round activity that must be carefully planned, continually monitored and attuned to meet fluctuating demand within the health sector.

**Table 4.2**

**Shelf-life of fresh blood products**

Fresh blood product	Specified shelf-life
Whole fresh blood (unrefrigerated)	24 hours
Red cells	up to 42 days
Platelets	up to 5 days
Frozen plasma	up to 12 months

Source: ARCBS, <[www.transfusion.com.au/blood\\_products/storage](http://www.transfusion.com.au/blood_products/storage)> [accessed 18 May 2011].

Note: The above shelf-lives apply to products that are stored according to the product specifications, as approved by the Therapeutic Goods Administration (TGA).

## The basis of the NBA–ARCBS contractual arrangement

**4.4** The NBA and the Australian Red Cross Blood Service (ARCBS) each have a central role in managing Australia’s fresh blood supply. Notwithstanding the repute of the ARCBS as a monopoly supplier, the relationship between the two parties operates as a purchaser–provider arrangement (refer to previous Figure 3) with terms and conditions defined through the Deed.<sup>94</sup>

<sup>94</sup> The Australian Red Cross Blood Service (ARCBS) is the operational arm of the ARCS responsible for blood services and products. For simplicity, ARCBS is used in this chapter when referring to the Deed and related matters, rather than ARCS.

#### 4.5 Key requirements underpinning this arrangement are:

- the Australian governments' national blood policies and processes, which are largely defined through the National Blood Agreement. These include primary policy objectives for the provision of an 'adequate, safe, secure and affordable' supply of blood products and services, and secondary policy aims which include maintaining 'voluntary non-remunerated donations of whole blood and plasma', promoting 'national self-sufficiency', and providing products to patients 'free of charge...';
- the Australian Health Ministers' Statement of Expectations which outlines the Australian governments' expectations of the ARCBS under the Deed;
- various regulatory requirements managed through the Therapeutic Goods Administration (TGA), pertaining to the quality, safety and efficacy of blood products; and
- the Commonwealth's administrative frameworks, which require contractual arrangements to function in accordance with the principles of sound contract management and demonstrate efficiency, transparency, accountability and value for money.<sup>95</sup>

4.6 The NBA and ARCBS are expected to embed these policies and principles into their formal working relationship. The contract (Deed) itself is a means of presenting essential information to support each party in carrying out their roles effectively, to meet contract (and thereby broader program) outcomes.

### **Defining value for money for fresh blood products and services**

4.7 In its management of the ARCBS arrangement, the NBA is expected to represent the interests of the Australian, state and territory governments and ensure that the ARCBS meets its contractual obligations, particularly the defined deliverables, to provide governments with cost-effective fresh blood arrangements. To accomplish this, it is essential that the Deed between the NBA and the ARCS clearly states the principles, goals, and deliverables of the

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<sup>95</sup> *Commonwealth Procurement Guidelines*, Financial Management Guidance No. 1, December 2008.



arrangement and the standards to which products and services should be provided.

**4.8** In line with the Commonwealth Procurement Guidelines' mandatory procurement procedures, the procurement of fresh blood products should also meet the principal requirement of value for money.<sup>96</sup> To meet national supply requirements, the ARCBS is required to deliver blood products and services to the standards set in the Deed, while being cognisant of value for money principles. Governments' expectations in this regards are outlined in Table 4.3.

**Table 4.3**

### **Defining value for money for fresh blood products and services**

The governments' interpretation of value for money in relation to the Deed has been articulated by the Minister for Health and Ageing as:

The provision of products and services through the collection, production and distribution of fresh blood products and services that meet regulatory requirements, while to the maximum extent possible, making cost benefit decisions within a finite health budget to achieve:

- the lowest possible cost of collection, processing and distribution;
- the maximum use of donated blood;
- delivery of products in accordance with the requests of jurisdictions with a priority being responsiveness to clinical demand; and
- effective mitigation of the risks of not meeting governments' supply plan.

The new Deed of Agreement (with the ARCS) will guide the appropriate day-to-day management of the service by the ARCBS within an enhanced reporting framework that gives governments confidence of the effective and efficient use of funds and the delivery of products and services required by states and territories for the delivery of clinical services.

Source: Letter to ARCBS from the Minister for Health and Ageing, Honourable Nicola Roxon MP, 21 October 2008.

Note: On 25 October 2010, the Minister for Health and Ageing (on behalf of all Health Ministers) provided a Statement of Expectations to the ARCS/ARCBS covering the period 1 July 2010 to 30 June 2013. In this statement, value for money also included two additional points: security of supply to meet the needs of the sector; and the most appropriate use of blood and blood products for patient outcomes.

## **Environmental factors**

**4.9** A range of environmental factors have contributed to shaping the NBA–ARCBS relationship and the focus of the Deed.

**4.10** The multi-jurisdictional nature of the blood sector, for example, presents operational differences in terms of blood sector organisation, administration and funding arrangements. The ARCBS and the NBA have to

<sup>96</sup> *Commonwealth Procurement Guidelines*, Financial Management Guidance No. 1, Appendix A: Exemptions from Mandatory Procurement Procedures, December 2008, pp. 50–51.

operate in consideration of these differences, and tailor services to meet individual state and territory needs. At times, however, this can be seen as inconsistent with a national approach to service delivery or as favouring one jurisdiction over another.

**4.11** National policy objectives envisage an ‘affordable’ blood supply. Rising costs continue to be a driver for blood sector reforms geared towards further efficiency and improved clinical use. However, new clinical uses and client demand also compel governments to fund quality or safety measures for fresh blood products and processes; which in turn contributes to increasing blood supply costs.

**4.12** As products are provided free to patients, monitoring of usage patterns and identification of product wastage is required to inform efficient use and cost containment strategies. The involvement of Approved Health Providers and the implementation of systems to support appropriate national tracking of product ordering, use and wastage are crucial in making this approach plausible. While the 2006–09 Deed attempts better scrutiny through improved management of ordering, distribution and stock levels (inventory), a much more strategic and considered approach to national end-to-end product use, monitoring and analysis is necessary to see benefits in this area.

**4.13** Giving due consideration to the above context and the complexities that the blood sector presents, the ANAO assessed the contractual arrangements between the NBA and the ARCBS in terms of:

- the effectiveness of the purchaser–provider relationship;
- the appropriateness of the Deed of Agreement; and
- meeting key contract deliverables.

## The effectiveness of the purchaser–provider relationship

**4.14** The NBA’s responsibilities in negotiating and managing the Deed, on behalf of the Australian governments, are not unlike other government arrangements for third party provision of services, as articulated below.

The implementation of policy is increasingly contracted out and delivered through the private and ‘third’ sectors, with the public service retaining responsibility for oversight, evaluation and accountability.

The success of outsourcing depends, to a large extent, on the ongoing collaboration between the public service and delivery agents. It calls for relationship management in order to facilitate social innovation and improvement over the long term. A contractual relationship based on rigid compliance to prescriptive administrative guidelines has the potential to be transformed by collaboration.<sup>97</sup>

**4.15** The ANAO examined how the NBA–ARCBS relationship was managed, and whether this provided a sound basis for effective contract implementation and blood sector improvements.

### An evolving partnership

**4.16** The relationship between the NBA and ARCBS has been an evolving partnership, at times strained in its inception. This was not unexpected given the different cultures and perspectives of the two entities; one a long-established organisation and community icon, and the other a more recently established government agency with a mandate encompassing greater blood sector efficiency and accountability.

**4.17** The ARCBS has a longstanding role in Australia’s blood sector, visible, for example, in managing Australia’s blood donation system and helping to position Australia for self-sufficiency.<sup>98</sup> Though largely funded by governments, the ARCBS has been responsible for delivering blood services across Australia for many decades, operating in a mostly autonomous way. The additional rigour and accountability that governments stipulated once the NBA was established posed a major challenge for the ARCBS administratively, operationally and culturally.

**4.18** As the new national coordinating agency, the NBA’s role included implementing a significant change agenda for the blood sector, flowing from

<sup>97</sup> Peter Shergold, Secretary of Prime Minister and Cabinet, Address to Senate Committee in 2005.

<sup>98</sup> op. cit., The Stephen Review, 2001, pp. xi, 13 and 75.

the Stephen Review. The NBA's credibility, however, had not been established in the blood sector, which contributed to initial barriers in gaining ARCBS acceptance of the governments' proposed change agenda. Similarly, the NBA was hesitant to accept ARCBS proposals without substantial justification of need. As a result, early relations were tenuous, with lengthy negotiations for many issues such as new funding models, Deed negotiations, project proposals and safety/quality measures.

**4.19** 'Relationship management underpins overall successful contract management' and 'the type of contract, its size, and duration as well as the culture of the parties and the personalities of the people involved will influence the relationship between the parties.'<sup>99</sup>

**4.20** The NBA-ARCS arrangement is complex, the organisations very different, and the business improvement agenda under the Deed and through various review recommendations was extensive.<sup>100</sup> Over its seven-year course, the NBA-ARCS relationship has matured to a large degree, allowing progress in a series of strategies to improve the efficiency of Australia's blood sector.

### **Establishment of a formal NBA-ARCS Deed of Agreement**

**4.21** The establishment of the NBA in 2003 provided a mechanism for national management and oversight of the blood supply through service delivery contracts.<sup>101</sup> However, early contracting between the NBA and the ARCS/ARCBS was a challenging and protracted process, and it was not until August 2006 that a formal Deed of Agreement was executed (Figure 4.1).

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<sup>99</sup> ANAO Better Practice Guide—*Developing and Managing Contracts*, 2007, p.76.

<sup>100</sup> KPMG, *Australian Red Cross Blood Service Business Study Final Report*, 2008; and see Appendix 5 for a list of reviews.

<sup>101</sup> *National Blood Authority Act 2003*, section 8(e), p. 4.

**Figure 4.1****Timeline—establishing a Deed of Agreement**

<b>Pre-July 2003</b>	Negotiations on a service and funding Deed of Agreement had stalled between the Department of Health and Ageing (DoHA) and the ARCS, in part owing to issues relating to funding for development of three major east coast principal manufacturing sites and indemnification of ARCBS risks. <sup>102</sup>
<b>1 July 2003 to 30 June 2005</b>	ARCBS provided products and services under a Letter of Agreement with the NBA (which incorporated an unexecuted Deed of Agreement). <sup>103</sup> Negotiations continued.
<b>1 July 2005 to 20 August 2006</b>	ARCBS provided products under a Contingency Supply and Funding Agreement with the NBA. Negotiations continued.
<b>21 August 2006 to 30 June 2009</b>	The first formal NBA and ARCS Deed of Agreement (the Deed) was signed, some three years after the NBA was established. This was a three-year Deed with an extension clause.
<b>1 July 2009 to 30 June 2010</b>	The 2006–09 Deed was extended to allow the design, negotiation and implementation of an Output Based Funding Model and negotiations towards a new Deed.
<b>1 July 2010 to 30 June 2011</b>	Further extension to allow negotiations for a longer term Deed. As at June 2011 the negotiations towards a new Deed were continuing.

Source: ANAO analysis.

**4.22** The 2006–09 Deed was signed by both parties, but with the knowledge that some obligations of the Deed could not be met at that time.

the parties acknowledge that some obligations of the ARCBS under this Deed do not reflect ARCBS capacities at the time of entering into the Deed, and will be achieved on a transitional basis....to allow ARCBS to build the necessary capacity or capabilities, or to implement specific enabling systems or activities.<sup>104</sup>

**4.23** Many key requirements were modified and extensive transitional provisions were set out in the Deed, including plans or aims to develop appropriate systems over the life of the agreement. While a large proportion of the intended tasks were undertaken, some progressed little during the operation of the 2006–09 Deed (see Table 4.4 and Chapter 6), suggesting that the capacity of either or both parties to meet obligations over the three-year period had been overestimated.

<sup>102</sup> Briefing Note to Minister Roxon, March 2008, from NBA files.

<sup>103</sup> NBA and ARCS Deed of Agreement, p. 5.

<sup>104</sup> *ibid.*, schedule 11, p. 165.

**Table 4.4**

**Progress of planned ARCBS tasks identified in the 2006–09 Deed**

Requirement under the Deed	Status and ANAO comment
<b>The ARCBS was to:</b>	
<b>Develop a strategic plan</b>	<b>Completed in 2009.</b> The ARCBS Strategic Plan is publically available. It is well aligned to government aims and policies, and recognises the dynamic nature of the blood sector, national/international challenges and achieving value for governments' investment.
<b>Prepare a Strategic Capital Investment Plan (SCIP)</b>	<b>Completed.</b> The SCIP details the intended capital expenditure required to sustain fixed assets. The first SCIP was completed in November 2005. It is a three-year plan, reviewed and updated annually.
<b>Prepare an Annual Capital Plan (ACP)</b>	<b>Completed.</b> In 2005 the ARCBS submitted an ACP, which was approved by the Jurisdictional Blood Committee (JBC) as part of the National Supply Plan and Budget. Since 2009, this has been submitted as part of the rolling three-year SCIP.
<b>Produce an Annual Report</b>	<b>Completed.</b> ARCBS provided Annual Reports to the NBA in hard copy from 2003–04 until 2008–09. The 2009–10 Annual Report was published on the ARCBS website.
<b>Develop a register of the AHPs</b>	<b>Completed.</b> The ARCBS developed a register of AHPs. This was provided to the NBA and is now updated monthly.
<b>Partake in third party reviews (see below)</b>	<b>Amended and largely completed.</b> Requirements were changed. A more extensive business study was completed in 2008. Other reviews were waived, subsumed into ARCBS internal audit program, or postponed pending new Deed negotiations.
<b>Report against the Key Performance Indicators (KPIs)</b>	<b>Largely completed/ongoing development.</b> Reporting accurately against all KPIs is affected by limitations in data collection capacity, which is currently being developed [see Chapter 6].
<b>Develop various protocols</b>	<b>Largely completed by 2010.</b> Of ten protocols, five were required under the Deed. Of these, two were completed but not signed, two were subsumed into other protocols and one required amending in the Deed. Also see Appendix 5.
<b>Development and implementation of an output based funding model</b>	<b>Partially completed.</b> Implementation of an OBFM did not meet the (revised) 1 July 2009 deadline. Although 'implemented' on 1 July 2010, the model is still being piloted and refined, and data elements are not finalised.
<b>Implement Change Pool Funding Program Proposals</b>	<b>Largely completed in 2010.</b> In 2009, the JBC approved an extension until 30 June 2010 to complete 75 per cent of the progressing Change Pool Funding Programs (these are to aid ARCBS transition to a national operation).
<b>Develop a hand-over plan</b>	<b>Not done.</b> Little progress has been made to date. This item is now part of the new Deed negotiations.
<b>Develop an agreement with AHPs for national standards and inventory</b>	<b>Not done.</b> A service level standards pilot was attempted in 2008. The NBA anticipates developing standards as part of the new Deed negotiations.
<b>Establish a Research and Development Committee</b>	<b>Partially completed.</b> A Research and Advisory Committee meets biannually, and the NBA reviews ARCBS research and development project proposals. The NBA advised the ANAO that the NBA and ARCBS are jointly developing a national research and development framework as part of the Deed negotiations.

Source: ANAO assessment from NBA records and the Deed of Agreement.

Note: The above list is not exhaustive. For information on data systems see Chapter 6.

**4.24** The variable progress of the Deed's key planned undertakings (also see Chapters 2 and 6) emphasises the importance of focused consultation and development of change management strategies that include clear priorities, responsibilities and allocation of resources. In moving to a new Deed, the NBA and the ARCBS would benefit from adopting a more structured, risk-based and collaborative approach to negotiating the Deed. Such an approach would include a systematic and well documented process with allocation of program priorities, and realistic timelines for the development, testing, and implementation of projects or new strategies under the Deed. This would better place both agencies to achieve their goals within the expected budgets and timeframes.

### **Review of ARCBS business**

**4.25** In line with Ministerial direction for 'effective and efficient use of funds and the delivery of products and services' (see Table 4.2), the 2006–09 Deed included provisions for reviews and strategies to improve the business efficiency of the ARCBS.

**4.26** A business study (review) was commenced in April 2007 to better position the ARCBS in meeting the obligations of the 2006–09 Deed. The study, which examined the business activities and operations of the ARCBS, was completed in January 2008 and made 35 recommendations for the ARCBS to improve its business processes.<sup>105</sup>

**4.27** The review's extensive recommendations amounted to a substantial change agenda for the ARCBS, involving modifications to its business practices. The ARCBS acknowledged the need to strengthen its business, agreed to implement the report's recommendations, and by December 2010 had implemented all but one of the recommendations.<sup>106</sup>

**4.28** A key recommendation of the 2008 review related to the development and implementation of an Output-Based Funding Model (OBFM), which constituted a significant change to the funding arrangements for the provision of blood products and services by ARCBS. An OBFM was provisionally implemented on 1 July 2010. As of May 2011, some components of the OBFM

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<sup>105</sup> op. cit., *Australian Red Cross Blood Services Business Study* report, summary, January 2008, commissioned by the National Blood Authority.

<sup>106</sup> ibid., Recommendation 18, which relates to cross-subsidisation.

including substitution rules, data systems and data collection specifications, were still being negotiated or refined.

## The appropriateness of the 2006–09 ARCS Deed

**4.29** An important goal in contracting is to develop agreements that are fit for purpose, clear in their intent, with terms agreed by both parties. To achieve this often requires structured and intense negotiation, focusing on essential components and areas of potentially high risk, so that work can be planned and prioritised to give the best outcomes within the best possible timeframes.

**4.30** Where contracts involve multiple products and extensive services, such as with the NBA–ARCBS Deed, it is especially important to define expectations. Clarity in specifying the contract deliverables, risk mitigation and performance measures contributes to both parties reaching agreement on the services to be provided.

**4.31** The ANAO assessed the appropriateness of the 2006–09 Deed against criteria based on provisions expected for government service contracts. A subset of this analysis is illustrated in Table 4.5. Further explanation of areas where improvements would be beneficial follows the table.

**Table 4.5**

### ANAO assessment: appropriateness of the 2006–09 Deed provisions

Key provision/criteria	ANAO findings and comments
The Deed includes:	
<b>Objective and Outcome</b> Includes a clear objective focusing on the overall intention and expected outcomes of the contract.	<b>Met.</b> The Deed identifies objectives and five mutual goals, as well as NBA and ARCS specific goals. The first, 'saving and improving lives through a world class blood system' gives a clear indication of the level of outcome required of ARCBS and NBA through the Deed.
<b>Context of the agreement</b> Specifies the legislative and policy basis of the program, funding sources, and the legal obligations and expectations of the purchaser and provider.	<b>Met.</b> The Deed links to the National Blood Agreement, which outlines national policy objectives. It also provides a context for accountability, efficiency and transparency. The inclusion of any changes in national priorities or policy since 2006, and greater emphasis on the Ministers' expectations regarding value for money would be valuable additions to the next Deed.
<b>Roles and responsibilities are clearly defined</b> Gives clarity and direction for implementing the contract.	<b>Largely met.</b> There would be benefit in agreeing and better defining the nature and extent of the ARCBS's: advice role in relation to various blood sector stakeholders, including governments; and responsibilities in monitoring activities in the broader blood sector and the expected resource implications.
<b>Deliverables</b> Clearly specifies the required goods and services, including service level standards, and relevant quality, quantity and timeliness measures.	<b>Partially met.</b> While some specifications for key products and services are detailed, others lack sufficient information to determine the nature or more complexity of the service. The Deed would be strengthened by including a complete range of deliverables, including service level standards, targets and timeliness measures for the key deliverables.



<p><b>Performance measures</b></p> <p>Defines Performance Indicators (PIs), with links to deliverables and mechanisms to alert managers to potential problems.</p>	<p><b>Partially met.</b> Schedule 7 sets out Key Performance Indicators (KPIs) against which the ARCBS must report its performance quarterly to the NBA. The KPIs have reasonable program coverage but are mainly quantitative. The reach of ARCBS and NBA performance reporting would be strengthened by more qualitative indicators and reporting against these.</p>
<p><b>Funding arrangements are clear</b></p> <p>The contract includes transparent funding arrangements, including fee for service elements.</p>	<p><b>Met.</b> Schedule 6 contained the basis for payments to ARCBS, including a process for annual calculation of a Product Unit Payment (PUP) and arrangements for various adjustments, invoicing, and payments. The new deed would be expected to incorporate or annex the newly developed (completed) output-based funding model (OBFM).</p>
<p><b>Risk management including shared risks</b></p> <p>Identification of key risks and mitigations, including shared risks and responsible parties.</p>	<p><b>Partially met.</b> The 2006–09 Deed includes provision for a risk management plan. While a number of strategies are in place for managing risks, given the significant funding associated with ARCBS’s contract, a risk plan should be an annexed to the Deed. The plan would identify individual and shared risks, and allocate responsibility for monitoring, reporting and mitigation of these.</p>
<p><b>Privacy and confidentiality provisions</b></p>	<p><b>Met.</b> The Deed included clauses for privacy, confidentiality and intellectual property management.</p>
<p><b>Review and evaluation</b></p> <p>Encourages early consideration of review and evaluation needs (for example, data collection) so that a review can have a sound basis and be conducted on time.</p>	<p><b>Met for review and partially met for evaluation.</b> The Deed made several references to reviews. Though different to those originally proposed in the Deed, a series of reviews of the ARCBS and the blood sector were undertaken, and recommendations progressively implemented. Evaluation of specific government policies implemented under the Deed was less evident, with capacity for such activities dependent on future data capacity improvements.</p>
<p><b>Dispute resolution mechanisms</b></p> <p>A structured approach to managing the disputes and associated risks, to support timely resolution or appropriate escalation of significant issues.</p>	<p><b>Not met.</b> The dispute resolution mechanism (clause 59) lacks sufficient structure and detail given the essential nature of the services and substantial government funding. A protocol for dispute resolution, agreed by both parties, would strengthen the contractual relationship. Ideally this would include appropriate steps to manage minor and day-to-day issues, and escalation procedures with relevant delegation of responsibility for resolution.</p>
<p><b>Contact officers and contract manager are designated</b></p>	<p><b>Met.</b> The contract provides one contact officer from each organisation, for the purpose of formal notices. Additional contacts have since been specified.</p>
<p><b>Communication arrangements</b></p> <p>A structured and coordinated approach to communication between the parties, with clearly defined responsibilities and mechanisms for timely information exchange.</p>	<p><b>Partially met.</b> Schedule 5, part A, outlines the arrangements for ‘communication and reporting’. While an extensive schedule is provided for reporting and notification obligations, the general communication element is narrow in its content. A public affairs protocol (proposed in clause 3) was developed in December 2007, and revised in September 2008, but would benefit from further enhancement. Joint CEO meetings are held quarterly (as per clause 4). Also see Table 4.7.</p>

Source: ANAO analysis against criteria developed from ANAO Better Practice Guide—*Developing and Managing Contracts*, 2007; and ANAO Audit Report No. 41 2009–10, *Effective Cross-Agency Agreements*.

## The document and its content

**4.32** Some of the strengths and weaknesses of the Deed are evident in the above analysis (Table 4.5). Overall, the Deed is not an atypical contract and includes many essential elements consistent with government procurement guidelines and better practice.<sup>107</sup> It reflects the wide range of services undertaken by ARCBS, sets out a sound context, and contains relevant goals and objectives. The document is, however, markedly variable in its level of detail and clarity.

**4.33** The Deed contains shared goals (Table 4.6) as well as individual NBA and ARCBS goals, which provide clear intent for the contractual relationship.

### Table 4.6

#### Shared goals under the 2006–09 Deed of Agreement

The NBA and the ARCS share the following common goals in relation to the blood sector:

- saving and improving lives through a world-class blood system;
- creating an integrated, efficient and effective blood supply, having regard to the primary policy objectives and secondary policy aims set out in Part 1 of the National Blood Agreement;
- ensuring an adequate, secure, and safe supply of blood, blood related products and services to meet the needs of the Australian community, in accordance with the National Blood Arrangements established by Governments;
- improving equity of access to blood and blood related products and services throughout Australia and the covered Territories irrespective of the state or territory in which the individual lives, in accordance with their clinical need (while noting that the National Blood Agreement provides that states and territories may alter the range of blood and blood related products that are prescribed and received in their jurisdiction); and
- support and respect of Australia's voluntary non-remunerated donors and their contribution to a safe and adequate supply.

Source: An extract from the 2006–09 Deed of Agreement, p.15.

**4.34** The Deed is divided into a front-end overarching contract (Part A), detailed provisions (Parts B to N), and 11 schedules containing essential requirements. This structure makes the document relatively easy to navigate. However, several protocols, joint arrangements and various work instructions are also meant to support the Deed. Many of these were not in place when the Deed was signed in June 2006, and progress towards their development and endorsement by each party was slow (see Appendix 5). These omissions made the Deed incomplete and reduced its usefulness and transparency.

<sup>107</sup> ANAO Better Practice Guide—*Developing and Managing Contracts*, 2007; and ANAO, Audit Report No. 41 2009–10, *Effective Cross-Agency Agreements*.

**4.35** The agreed objective of the contracted services is given and the ARCBS’s functions are listed in Schedule 3 (Table 4.7).

**Table 4.7**

**Objective of Schedule 3—Products and ARCBS Functions**

‘Schedule 3 states the objective agreed by the Parties for continuing to develop and implement best practice nationally consistent processes within ARCBS in relation to products and services under this deed within the policy and funding frameworks established by governments to ensure that:

- ARCBS’ processes are transparent and accountable;
- the Australian blood system moves towards better integration between planning and demand;
- products required for the national supply plan are collected, processed, tested, ordered and distributed and otherwise managed in the most efficient and effective manner; and
- opportunities for wastage and expiry across the sector are minimised through a comprehensive inventory management framework.’

Source: Extract from Schedule 3, Part A, 2006–09 Deed of Agreement.

**4.36** This objective is reflected in the details of the functions and reporting requirements that constitute the schedules of the Deed. Schedule 3 describes the services to be performed by the ARCBS, and is therefore critical to the implementation of the contractual arrangements.

**4.37** In addition to those described above, schedules included:

- |                                                                                                                                                                                                                          |                                                                                                                                                                                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>• Schedule 4—Planning and review cycle;</li> <li>• Schedule 5—Communication and reporting;</li> <li>• Schedule 6—Payments;</li> <li>• Schedule 7—Performance measures;</li> </ul> | <ul style="list-style-type: none"> <li>• Schedule 8—Governance standards;</li> <li>• Schedule 9—Insurance;</li> <li>• Schedule 10—Deed of Security; and</li> <li>• Schedule 11—Transition.</li> </ul> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**4.38** Within most schedules there was adequate information to provide a basis for operations under the Deed. One exception was Schedule 5, Communication and Reporting, which for the most part focuses on reporting, rather than setting up mechanisms for good communication. A brief analysis of Schedule 5, together with other assessments of communication activities, showed the following (Table 4.8).

**Table 4.8**

**Schedule 5—Communication and reporting**

Strengths	Areas to improve
<ul style="list-style-type: none"> <li>• Detailed list of the required reports and the expected schedule for reporting included in the Deed.</li> <li>• ARCBS reporting covered a wide range of business: progress against the supply plan; planning and reviews; financial; annual reporting; horizon scanning and emerging trends; progress of policy implementation.</li> <li>• Reporting against deliverables and a range of KPIs included in the Deed.</li> <li>• Quarterly meetings between the two agencies' Heads.</li> <li>• Involvement of ARCBS in annual supply planning processes and stakeholder forums.</li> </ul>	<p>Specific areas for improvement include:</p> <ul style="list-style-type: none"> <li>• strengthening the public affairs protocol;</li> <li>• improving processes for issues/dispute resolution and clearly defining these in the contract;</li> <li>• mechanisms to provide ARCBS with better access to decision making committees, to ensure its representation on key issues affecting ARCBS, the blood supply, and public issues;</li> <li>• development of a succession plan in case of contract termination;</li> <li>• stronger linking of communication strategies to blood sector risks;</li> <li>• review the extent of reporting through assessment of risks, priorities and available resources.</li> </ul> <p>A joint NBA–ARCBS communication strategy could be beneficial to both agencies, particularly in clarifying communication responsibilities and identifying the information and key communication needs of broader blood sector stakeholders.</p>

Source: ANAO analysis and Schedule 5 of the 2006–09 Deed of Agreement.

**4.39** Recognising a need to strengthen communication, in 2008 the NBA and ARCBS organised a workshop to ‘agree a series of principles and processes to improve communication and the working relationship between NBA and ARCBS’. This action appears to have gone some way to strengthening the NBA–ARCBS interactions.

**4.40** There were, however, opportunities for greater recognition of the potential and contributions of each party to the blood supply arrangements. Given the ARCBS’s longstanding experience in the blood sector, and keeping in mind the Government’s intent in setting up the NBA (see Chapters 1 and 2), a stronger focus on partnership and collaboration could better place both organisations to achieve more effective and efficient operations into the future. Appropriate strategies to strengthen the contractual relationship, and the Deed, are included in Table 4.8 (above).

## Recommendation No.3

4.41 The ANAO recommends that the NBA strengthen its approach to managing the Deed of Agreement with the ARCBS by:

- clearly identifying the responsibilities, deliverables and service standards for each primary function specified under the Deed;
- developing a more representative set of Key Performance Indicators (KPIs) and targets to measure qualitative as well as quantitative aspects of the contract deliverables; and
- agreeing realistic timeframes and priorities for developmental work or research specified as part of the Deed.

NBA response: *Agreed*

## Meeting contract deliverables

4.42 A critical issue in contractual arrangements is striking an appropriate balance between the degree of purchaser oversight of service delivery and the operational flexibility of the provider. Specifying contracts in terms of outcomes or outputs, not inputs, allows the contractor room for innovation and consequent efficiency gains. The success of this approach is, however, contingent on:

- the purchaser clearly specifying the outcomes or outputs;
- both parties agreeing to appropriate service quality measures; and
- having in place the systems to collect sufficient data to enable such measurement.

4.43 In the 2006–09 Deed, Part C of Schedule 3 (Products and ARCBS Functions) lists the following main functional areas to be performed by the ARCBS.

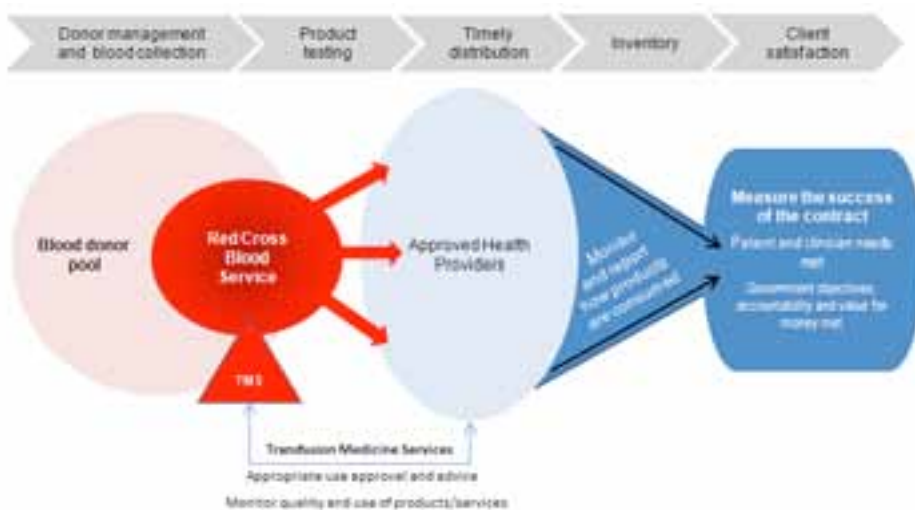
- |                                         |                                   |
|-----------------------------------------|-----------------------------------|
| • Donor management and recruitment      | • Operations support              |
| • Collections                           | • Transfusion medicine            |
| • Testing                               | • Research and development        |
| • Processing                            | • Corporate support and planning. |
| • Inventory management and distribution |                                   |

4.44 These broad functional areas are described to varying degrees of detail; from a list of seven short dot points for *Donor Management and Recruitment*, to ten pages of information on *Inventory*.

4.45 The ANAO examined key steps in ARCBS’s delivery of services and products, as indicated in Figure 4.2: donor management and blood collection, testing, distribution, inventory and client satisfaction. These five steps are particularly important in establishing a chain of services, ensuring the quality and delivery of those services, measuring blood product usage/wastage levels, and ensuring that outcomes can be (and are) measured to determine the effectiveness and efficiency of the services (including achieving value for money). The ANAO also checked a selection of reporting requirements under the Deed, to determine if these were being met.

**Figure 4.2**

**Contract requirements in managing fresh blood deliverables**



Source: ANAO.

Note: Arrangements between CSL and ARCBS for plasma are not specifically shown in this figure. However, it should be noted that ARCBS provides plasma to CSL for fractionation into plasma-derived products. These products are then delivered to Approved Health Providers by the ARCBS, when required, under the NBA–ARCBS Deed of Agreement.

**Activities and functions**

*Donor management and recruitment*

4.46 Donor management and recruitment is a key function of the ARCBS and a crucial component of the Australian donation-based blood system.

Despite this, information regarding this area was limited within the Deed, for example:

- Schedule 3 listed seven functions: donor recruitment and retention marketing; donor recognition; community education about donor health; community education about the ARCBS; donor contact, liaison and appointments; donor counselling and safety; and preparation of donor information materials<sup>108</sup>; and
- Schedule 7 contained an objective, 'maintain a sufficient donor base to meet the annual supply estimates', KPIs and the reporting requirements.<sup>109</sup> The frequency of reporting was annual for each KPI.

**4.47** Key Performance Indicators (KPIs) specified in Schedule 7 of the Deed were: size of donor base by type; annual donations by type; frequency of donation; and percentage of new donors. The ARCBS monitors these against annually planned targets and provides figures quarterly and annually to the NBA.<sup>110</sup> The Deed itself contains no information on how the annual targets are set.<sup>111</sup> Clarity in the methodology for setting of targets would ensure consistency and transparency in this area, to allow better comparison of data between years.

**4.48** Donor management has many components. The ARCBS monitors the number of new donors and the retention rates of donors in different age groups, which assists in forward planning and targeting of recruitment. However, the Deed contains no qualitative indicators for donor management. Performance against functions such as donor safety and donor satisfaction are largely uncaptured.

**4.49** ARCS Annual Reports and ARCBS reporting to the NBA against the KPIs show that donor numbers and total donations have risen over the last nine years, although the data were incomplete. The NBA has described the rise in donor numbers as insufficient to meet Australia's demand for plasma derived products, particularly Intravenous Immunoglobulin (IVIg).

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<sup>108</sup> op. cit., NBA-ARCS Deed of Agreement 2006-09 (the Deed), Schedule 3.

<sup>109</sup> ibid., Schedule 7, section 1.1, Donor management performance measure objective.

<sup>110</sup> NBA internal documents regarding forecasting.

<sup>111</sup> Schedule 7 of the Deed specified the annual reporting of donor management reporting, however, the NBA and ARCBS planning and target parameters specifies quarterly reporting.

**4.50** The ARCBS Donor Management—donor satisfaction target had been changed from 71 per cent to 44 per cent.<sup>112</sup> Maintaining a sufficient donor pool is an imperative for the ARCBS under the Deed. Low donor satisfaction could imply reducing donor confidence and impact on the future availability of donors. The ARCBS informed the ANAO that the 46 per cent reflected a change in reporting against its annual survey. This issue needs to be examined as part of the next Deed negotiations, with a view to setting a more informative target and improving the donor survey methodology.

**4.51** The lack of specifications for core donor recruitment and retention activities led to ambiguity in some funding matters. For example, in October 2007 the ARCBS sought JBC approval and funding for a Donor Relationship Program (DRP). The ARCBS presented the proposal as a means of achieving significant gains in donor retention and reduction in costs of donor recruitment, which, if realised, would result in savings to Australian governments. In considering the ARCBS proposal (in August 2008), the JBC raised concerns that ‘donor attraction and retention is a core function for the ARCBS under the Deed of Agreement’. The NBA notified the ANAO in December 2010 that the ARCBS had ‘still not implemented a donor relationship management program despite it being their core business’.

**4.52** The lack of detail in the Deed regarding donor management functions makes it difficult to determine what core activities were expected of the ARCBS and whether the ARCBS proposal exceeded the normal funded activities. The inclusion of clearer requirements and deliverables in the Deed would help to focus future planning and approval of proposals to address donor management issues.

### *Collections*

**4.53** Although collection of blood from donors is core business for the ARCBS, minimal information is provided for this function:

- the Deed lists eight functions: donor registration, selection and education; donor assessment and screening; blood collection; donor hospitality; collection recall; donor recall; emergency donor panel support activities; and freighting of collections to processing centres.<sup>113</sup>

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<sup>112</sup> *Australian Red Cross Blood Service Annual Report 2008–09*, p.26. The donor satisfaction target for 2008–09 was 44 per cent.

<sup>113</sup> *op. cit.*, The Deed, schedule 3.



- Schedule 7 contains some information on KPIs relating to blood collection under the heading of ‘supply chain management’ but these have little correlation to the eight functions mentioned above, concentrating mainly on the quantity of collections (for whole blood, whole blood derived red cells, and apheresis plasma units) for efficiency calculations.

**4.54** The inclusion in the Deed of additional information about the fundamental requirements of the eight collection functions, especially the standards expected, and targets or KPIs, would be useful in providing insight into the effectiveness and efficiency of this critical area of ARCBS’s business.

**4.55** The audit noted that the ARCBS has introduced several improvements to its collection activities in recent years. Many changes implemented under the 2006–09 Deed were intended to improve the safety or quality of blood products, and to meet international trends (Table 4.9).

**Table 4.9**

### Blood collection activities and improvements

Improvement activity	Description
<b>Introduction of apheresis</b>	Apheresis is a procedure in which blood is temporarily withdrawn, one or more components are selectively removed, and the remainder of the blood is reinfused into the donor. This allows more frequent donations and a greater volume of plasma and/or platelets to be collected from each donor. <sup>114</sup>
<b>Leucodepletion</b>	Leucodepletion is the removal of white cells from blood products to minimise adverse transfusion reactions. Leucodepletion for red cells was implemented on 1 October 2008.
<b>Strengthening of donor screening</b>	The ARCBS has a Donor and Product Safety Unit, which introduced changes to donor eligibility criteria to exclude residents in high risk areas of: dengue fever, malaria, and H1N1 influenza.
<b>Bacterial contamination screening</b>	The ARCBS presented a Business Case to the NBA in 2004, proposing measures to limit and detect bacterial contamination of platelets, and a move to pre-release testing of platelets. After further analysis, a bacterial contamination screening program was implemented in April 2008.
<b>Improving donor information and management</b>	ARCBS has introduced a National Contact Centre. <sup>115</sup>

Source: ANAO compilation from NBA records and ARCBS public documents.

<sup>114</sup> Australian Red Cross Blood Service, Discussion Paper—*A National Position on Plateletpheresis*, July 2008.

<sup>115</sup> ARCBS Strategic Plan, 2009, p. 15.

## Testing

4.56 The ARCBS is responsible for the testing of blood donations and transfusion patient specimens, to ensure the safety of the products. Payment for these services is covered by the Deed arrangements. However, the Deed itself contains almost no information on testing provisions, simply stating:

### Scope of testing

- testing of collections and donor/potential donor transfusion patient/potential transfusion patient specimens; and
- quality products.

4.57 The TGA has a regulatory role which encompasses the registration of blood products, inspection of manufacturing premises and various other regulatory functions such as product testing for compliance with quality, safety and efficacy standards. The ARCBS laboratories are also subject to other professional standards and accreditation processes.

4.58 Specifications for testing requirements, or reporting against set KPIs, were absent from the schedules or annexed to the Deed. The Deed also shed little light on interagency communication mechanisms for issues or problems arising from testing. Potential efficiency or performance issues like down-time or delays in testing, errors leading to re-testing of samples, recalls of products due to testing discrepancies or contamination which may impact on the continuity of supply, were largely not captured through the Deed.

4.59 Some sources of information on the quality and reliability of the ARCBS' testing activities were evident through ARCBS reporting mechanisms (Table 4.10). The NBA advised the ANAO that it intends to strengthen this area by pursuing greater clarity in the roles and responsibilities of all parties for testing as part of the new Deed negotiations.

**Table 4.10****Reporting the quality and reliability of testing**

Activity	Extent of reporting
Reporting to NBA and JBC by ARCBS of testing problems	The ARCBS reported new testing methods and monitoring of their effectiveness, for example, monitoring of positive results in the early implementation of bacterial testing.
Reporting of positive test results with implication to recall blood product/s	This can be as a result of ARCBS test results or reporting from clinicians who detect illness in people post-donation. For example, Hepatitis A contamination of plasma for fractionation resulting in discarding of plasma.
Adverse reaction reports	Reporting of blood recipient reactions to contaminated products. There are mechanisms through the Therapeutic Goods Administration (TGA) for reporting contaminated or faulty products.
Papers provided to JBC by ARCBS	For example the business case for bacterial testing of platelets and the introduction of leucodepletion.
A Memorandum of Understanding (MOU) between the NBA and TGA for the Cooperation and Exchange of Information	Signed by TGA and NBA in June 2007, the MOU sets out guidance for the two agencies to exchange information, including 'information relating to product defects, which may have blood and blood products supply implications (for example, recall, and adverse events)'. While current, the MOU was not implemented on a regular basis. Communication with TGA was on an as needed basis.

Source: ANAO.

*Distribution and inventory*

**4.60** The Deed requires the ARCBS to distribute blood products to Approved Health Providers (AHPs) and maintain records for the management of inventory and distribution of products. These functions enable the ARCBS to monitor product consumption and demand so that adequate collection of blood (and manufacturing of products) can be initiated to fulfil demand and any target requirements. Under the Deed, inventory is a primary source of information about ongoing product demand, use and wastage.

**4.61** The ANAO examined whether the inventory arrangements were able to provide a comprehensive picture of product distribution and use. It also examined KPIs for these activities.

**4.62** ARCBS inventory functions include developing and updating an annual supply plan, and maintaining records of (not an exhaustive list):

- the amount of product produced by ARCBS and distributed to AHPs;
- the volume, testing results, reconciliation and delivery of products for fractionation;
- ordering and receipt of products from other National Blood Suppliers;
- product tracking and monitoring of inventory levels;
- maintenance of the Approved Health Provider List; and
- product recalls.

4.63 To support the inventory functions, the 2006–09 Deed included the following requirements (Table 4.11).

**Table 4.11**

**Deed requirements for improving distribution and inventory**

Requirement	Ability to meet the requirement
<b>Develop a system for establishing and reviewing appropriate target ranges for products held by the ARCBS and Approved Health Providers (AHPs) (Clause 14.2).</b>	<b>Not met.</b> No system is in place. The NBA and ARCBS in 2008 attempted to pilot Service Level Agreements between the ARCBS and jurisdictions. The pilot, however, did not progress.  The NBA reported that it is now progressing a national inventory framework, in conjunction with ARCBS, as a part of the new Deed negotiations.
<b>Meet delivery times specified in an order (Clause 20.3).</b>	<b>Not met.</b> There are no targets or standards set under the Deed. It was not clear whether minimum delivery times were set, or how performance was measured.  During the audit the NBA advised that it was seeking to address this through its draft National Service Standards and Requirements, being developed for the new Deed.
<b>Maintain a control system which will allow tracking of the specific location of products up to the point of supply to the AHP (Clause 15.4).</b>	<b>Met.</b> Since 2008, product movements and resulting ARCBS inventory has been recorded in the Blood Service's National Blood Management System (NBMS). Inventory is tracked in NBMS at a location ('depot') level corresponding with the physical holding. Reporting of inventory by depot is undertaken from both NBMS and the ARCBS data warehouse ('CIMAR').
<b>Provide inventory reports to the NBA in accordance with Schedule 5 communication and reporting (Clause 15.4.5).</b>	<b>Largely met.</b> The ARCBS provides daily red cell inventory reports to the NBA, and other monthly (Group 3 and 4) product inventory reports. The quality of the data is dependent on the ability of individual AHPs to monitor inventories, and the type of systems in place.  NBA reported that improvements are underway through the introduction of ORBS (see Chapter 6).

Source: ANAO assessment and NBA responses to the audit Issues Papers.

4.64 Inventory activities are to a large degree dependent on the capacity of the AHP to monitor receipt, storage and use of the blood products. The quality and diversity of IT systems and the limited resources to support inventory activities has, over the years, contributed to incomplete data from the AHPs, states and territories.

4.65 The Ordering and Receipting Blood System (ORBS) is a receipting and verification data system, designed to acquit blood supply invoices against known orders and deliveries.<sup>116</sup> This recently developed system, while for national inventory purposes, is not used by all states and territories (also see Chapter 6).<sup>117</sup> This means that the NBA is not in a position to accurately assess

<sup>116</sup> From early 2011, after further development, the ORBS became BloodNet.

<sup>117</sup> Data capacity issues are also dealt with in Chapter 6.

the delivery of blood products, the volume of products used or wasted, or the appropriateness of product use.

**4.66** In addition, the Deed contained little information on what constituted wastage, or the basis on which this was being reported. For example, wastage of blood products may be due to:

- ARCBS discarding products due to: manufacturing error; unfavourable test results; over-collection or over production; expired products returned to ARCBS; problem with delivery or cold chain integrity; and
- AHP over-ordering or inappropriate stocking; burst blood bags or incorrectly prepared products; poor storage and spoilage.

**4.67** The NBA, in consultation with the ARCBS and AHPs, should develop clear definitions for various forms of wastage, including how each is dealt with in terms of funding, responsibility, reporting and strategies to reduce their relative incidence (see Recommendation 4).

### *The Transfusion Medicine Services*

**4.68** The Transfusion Medicine Services (TMS) is a key service provided by the ARCBS under the Deed. The ARCBS describes the TMS in the following way:

The Transfusion Medicine Services (TMS) is a small national multidisciplinary transfusion team (medical, nursing and scientific with administrative support) available 24 hours, 7 days per week. The team is an integral part of the work of ARCBS, recognising and responding to clinical needs and providing medical expertise into the organisation, thereby resulting in improved patient outcomes, reduced risk, reduced waste and improved cost efficiency. The TMS team adds value to Australian transfusion practice at the individual patient, institutional, jurisdictional and national level in hospitals, clinics and laboratories across the country. The TMS team works with governments, special societies, educational institutions and other bodies, providing expertise and data to inform policy development and implementation, education and training, resulting in improved practice and outcomes for the sector.<sup>118</sup>

**4.69** For 2008–09, the ARCBS estimated the funding for TMS at \$5.2 million, just 1.3 per cent of overall funding for national blood services under the ARCBS contract. This funding supports approximately 30.3 Full-Time Equivalent TMS staff, consisting of 8.5 medical, 4.9 scientific, 8.2 nursing staff, 2.3 managers and 6.4 administrative staff.

<sup>118</sup> Detailed description of services provided by the ARCBS to the NBA, June 2009, p. 1. Also see Appendix 6.

**4.70** The 2008–09 Deed listed 14 broad functions of the TMS (see Appendix 6) but lacked detailed specification or KPIs against the scope of the service deliverables. Schedule 7 of the Deed contained one KPI with a TMS component (Table 4.12).

**Table 4.12**

**Transfusion Medicine Services Key Performance Indicator**

KPI			
AHP satisfaction with ARCBS services			
<b>TMS specific component</b>	Availability of transfusion medicine advice	Quality of transfusion medicine advice	Availability, quality and adequacy of transfusion medicine materials provided
<b>Frequency of reporting</b>	Annual		
<b>Definition and method</b>	Percentage of surveyed respondents reporting good or higher levels of satisfaction in each of the service domains.		

Source: 2006–09 NBA–ARCBS Deed of Agreement.

**4.71** When the 2006–09 Deed was signed, the NBA did not have a good account of the TMS services provided to the states and territories. The subsequent 2008 Business Study of the ARCBS suggested that:

Subject to clarification of the role [of TMS] in each jurisdiction, potential savings might be possible through a rationalisation of this service and/or through a mechanism by which states and territories desiring the clinical advice component of this service fund the service as a 'value add' outside of the Deed arrangements.<sup>119</sup>

**4.72** In response to the Business Study comment (above), the NBA requested the ARCBS to undertake an extensive itemisation of the TMS's activities so that NBA could 'gain a more comprehensive understanding of the TMS and its key functions'. The NBA also asked the states and territories (through the JBC representatives) to identify services provided to their jurisdiction by the TMS.

**4.73** The effort that parties put into this exercise was quite extensive in relation to the proportion of funding involved. Nonetheless, the activities helped to clarify TMS functions, which should better place the NBA in incorporating TMS functions into the next Deed.<sup>120</sup>

<sup>119</sup> op cit., *Australian Red Cross Blood Services Business Study* report, January 2008.

<sup>120</sup> At the time of the audit, the NBA and ARCBS were negotiating new funding arrangements for the TMS.

## Customer (client) satisfaction

4.74 ARCBS clients (in the context of the Deed) can be grouped into the following categories (Table 4.13).

**Table 4.13**

### Client categories

<b>Governments</b>	As funders of blood services, the Commonwealth and state and territory governments are clients of the ARCBS. They are the purchasers in the contractual arrangement, while ARCBS is the provider of services.
<b>Hospitals and other AHPs</b>	These are receivers of ARCBS products and services. ARCBS also supports these through expert advice, education and training activities.
<b>Patients</b>	The ultimate recipients of transfusion products are the patients. It is not always possible for patients to recognise or assess the quality of a transfusion service. However, service quality can be monitored through adverse reaction reports and other hospital based reporting.
<b>Specialist groups</b>	The collective voice of groups of clients with special transfusion needs. Cost implications and changes in products mean that these groups may be affected by changes to government policy. These are clients of the ARCBS and NBA (as representative of governments).
<b>Blood donors</b>	Donors are direct clients of the ARCBS, as well as being the ARCBS's supplier. This makes the relationship between the donors and the ARCBS unique, and very interdependent.

Source: ANAO.

4.75 The NBA–ARCBS Deed contains little to elucidate client groups in terms of needs, expectations or priorities, although it does require the ARCBS to conduct stakeholder surveys on:

- the satisfaction of AHPs with ARCBS services (Table 4.14); and
- donor satisfaction with ARCBS services.

**Table 4.14**

### Case study

#### ARCBS survey of Approved Health Providers

The ARCBS conducted a client survey in 2008. The survey asked six questions relating to AHP satisfaction with services provided by the TMS. Participants were asked to respond to each question using a 1 to 10 rating (where 10 was the highest level of satisfaction and 1 was the lowest level). AHP participation was voluntary.

**ANAO analysis:** The survey design lacked context. The states and territories (and AHPs within states) receive different services based on individual needs, situations or service availability. The survey did not consider the extent to which the services had been utilised in conjunction with the level of satisfaction experienced. This same limitation was evident in other groups of questions in the survey (that is, relating to areas of ARCBS other than TMS).

The survey also made no attempt to seek responses for the individual disciplines/components within TMS, such as medical, scientific or nurse based advice/service. Information about specific services and the strengths or weaknesses within these groups would assist in planning and targeting TMS services.

**4.76** The NBA has no systematic independent approach for monitoring stakeholder satisfaction: it has no register for monitoring complaints, does not track the timeliness of responses to issues raised through the blood committees and has no direct feedback mechanism from AHPs. While the NBA does have constant interaction with the states and territories through the JBC representatives, there had not been a strong focus on monitoring the issues raised.

**4.77** Given the limited mechanisms in place to engage stakeholder groups<sup>121</sup>, gain insight into client satisfaction or assess their essential needs, it would benefit the NBA and ARCBS to consider the inclusion of periodic and well-designed surveys into the new Deed arrangements. These measures would provide valuable information for service improvement and efficiencies.

## Recommendation No.4

**4.78** To help inform the NBA's assessment of the ARCBS's performance under the Deed of Agreement, the ANAO recommends that the NBA, in consultation with the ARCBS, Approved Health Providers and other key stakeholder groups:

- develop and implement definitions for the various forms of blood product wastage, and a strategy explaining how wastage should be dealt with in terms of funding, responsibility, reporting and incident reduction; and
- employ periodic client surveys to provide information that will identify opportunities for service improvement and efficiencies.

NBA response: *Agreed*

## New Deed of Agreement

**4.79** The 2006–09 Deed provides a reasonable basis for development of a new Deed, recognising that improvements are necessary to make it a more complete and self-contained account of the arrangements between the NBA and the ARCBS. Although a sizable body of work was completed under the 2006–09 Deed, several tasks identified therein were implemented later than

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<sup>121</sup> This includes representatives of various professional and blood product user groups on NBA or JBC committees, product supplier forums, and opportunities for input into guidelines through public consultation processes.



expected, and some are still to be completed or commenced. Lessons from this experience should help to inform the NBA and the ARCBS in requirements for a new Deed.

**4.80** In negotiating and developing substantial Deeds (such as this one), the NBA and ARCBS would benefit from a more systematic and risk-based approach to identifying key priorities and specifying key deliverables. To strengthen Deed management and assurance around deliverables will require a greater focus on specifying deliverables and service standards, agreeing funding mechanisms and realistic timelines, as well as the inclusion of qualitative KPIs and more structured and collaborative communication mechanisms.

**4.81** The consideration of risk management is particularly important, given the complex nature of the supply arrangements and the proposed new framework for the Deed: a nine year high-level legal agreement; a three year funding and service agreement; and an annual Service Delivery Plan (SDP) that defines governments' requirements and priorities on a three year basis in line with governments' Statement of Expectations.<sup>122</sup> Particular consideration will need to be given to how the Deed will be maintained and updated, and to establishing suitable mechanisms for regular structured communication to discuss and resolve significant issues as they arise, being mindful to avoid unnecessary complexity or red tape.

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<sup>122</sup> The Statement of Expectations for the ARC/ARCBS was endorsed by Governments in October 2010. It covers 2010–11 to 2012–13.

## 5. Commercial Contract Management

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*This chapter examines the National Blood Authority's (NBA's) approach to managing commercial contracts, using the example of its contract with Baxter Healthcare Pty Ltd for the supply of Defined Blood Products.*

### The National Blood Authority's commercial contracts

**5.1** Australia's supply of fresh blood for patients is complemented by the provision of various commercially sourced blood products. The Australian plasma fractionating company, CSL Ltd, is the major commercial supplier of Australia's blood products, with most of its products derived from Australian blood donations. However, a significant number of Australians are treated with imported blood products that either:

- are not produced locally, such as laboratory engineered recombinant blood products not derived from human plasma (for example, recombinant clotting Factor VIII); or
- are intended to supplement the domestic supply of plasma-derived products (for example, intravenous immunoglobulin).

**5.2** The NBA is responsible for ensuring that Australia's blood supply needs are met through appropriate contracting for the full range of products required by Approved Health Providers.

**5.3** This chapter focuses on the commercial aspects of the NBA's contracting functions, which includes contracting for the supply of plasma and recombinant blood products with overseas pharmaceutical companies.

**5.4** Table 5.1 shows the National Blood Authority's (NBA's) 2009–10 commercial contracts for blood products.

**Table 5.1****NBA contracted commercial suppliers of blood products in 2009–10**

Supplier	2009–10 Contract value and products provided
<b>CSL Ltd</b>	\$186.16 million for various: albumin, clotting factors, immunoglobulins, and diagnostic reagents
<b>Baxter Healthcare Pty Ltd</b>	\$90.62 million for Factor VIII (two products), Factor VII Concentrate, Factor Eight Inhibitor Bypass Agent (FEIBA), Protein C and Anti-Rh (D) Immunoglobulin
<b>Pfizer Australia Pty Ltd (was Wyeth Australia Pty Ltd)</b>	\$48.94 million for Factor VIII and Factor IX
<b>Novo Nordisk Pharmaceuticals Pty Ltd</b>	\$26.42 million for Factor VIIa
<b>Octapharma Pty Ltd</b>	\$48.69 million for intravenous immunoglobulin (IVIg)
<b>Lateral Grifols Pty Ltd (was DiaMed Australia Pty Ltd)</b>	\$0.81 million for diagnostic reagent products
<b>Ortho-Clinical Diagnostics (Johnson &amp; Johnson Company)</b>	\$0.43 million for diagnostic reagents
<b>Abacus ALS Pty Ltd</b>	\$0.04 million for diagnostic reagents

Source: ANAO using data from NBA Annual Report 2009–10.

## Defined Blood Products

5.5 The Australian haemophilia community is served by the NBA's management of contracts with large commercial suppliers for a group of Defined Blood Products (DBP).<sup>123</sup> A number of these products are laboratory engineered. The NBA's 2006–2009 contract with Baxter Healthcare Pty Ltd (Baxter) is the largest of three for these DBP. The contract was operational at the time of the audit, providing the products specified in Table 5.2.

<sup>123</sup> The NBA now refers to Defined Blood Products (DBP) as Imported Plasma and Recombinant Products (IPRP). As DBP was the term used for much of the period audited, for simplicity, the ANAO has used this term throughout the audit report.

**Table 5.2****Defined Blood Products supplied by Baxter at 30 June 2010**

Product type	Product name	Use
Recombinant Factor VIII	<ul style="list-style-type: none"> <li>• Advate</li> <li>• Recombinate</li> </ul>	Prevention and control of haemorrhagic episodes in haemophilia A (Factor VIII deficiency) patients
Factor VII concentrate	Factor VII concentrate	Treatment of bleeding episodes in people with Factor VII deficiency
Anti Inhibitor Coagulant Complex Concentrates	Factor Eight Inhibitor Bypass Agent (FEIBA)	Treatment of bleeding episodes including surgical interventions in haemophilia A and B patients with inhibitors
Protein C	Ceprotrin	Treatment of haemorrhagic conditions associated with congenital Protein C deficiency
Anti-Rh (D) Immunoglobulin	WinRho	Prevention of a potentially fatal form of anaemia in newborn babies of Rh (D) negative mothers

Source: ANAO based on information in the NBA's 2009–10 Annual Report and its contracts and fact sheets.

**5.6** The NBA entered its contract with Baxter in 2006 following an approach to the market in 2005. Although it was varied in 2009 and extended until 30 June 2011, the contract did not change materially. The audit encompassed the NBA's work with Baxter from 2005 to the present.<sup>124</sup>

**5.7** To give insight into the NBA's approach to commercial procurement and ongoing contract management, the ANAO examined the Baxter contract in terms of:

- consistency with government procurement policy;
- design of the deed with Baxter; and
- ongoing management of the contract.

<sup>124</sup> During the audit, the NBA issued a Request for Tender to ensure that new contracts for DBP were in place from 1 July 2011. On 6 June 2011, the NBA announced the outcome of this procurement: from 1 July 2011, Baxter no longer supplies recombinant Factor VIII (rFVIII) products (the most significant of the group) or WinRho, but continues to provide FEIBA, Ceprotrin and Plasma Derived Factor VII. From 1 July 2011, rFVIII products are supplied by Bayer and Pfizer. Source: <<http://www.nba.gov.au/supply/iprp-tender-outcomes.html>>

## Consistency with government procurement policy

**5.8** The *Commonwealth Procurement Guidelines* (CPGs) establish the Australian Government's procurement policy framework and articulate the Government's expectations of all FMA agencies in performing duties relating to procurement. The CPGs establish principles that apply to all procurement processes, with value for money being the core principle.<sup>125</sup>

**5.9** Central to the CPGs is the identification of procurements valued at over \$80 000 as 'covered procurements', to which the Mandatory Procurement Procedures (MPPs) in Division 2 of the CPGs apply. These mandatory procedures require 'covered procurements' to include open, select or direct source tendering, unless a specific exemption applies.

**5.10** While the procurement of blood and related products must demonstrate value for money, procurement of blood plasma products or plasma fractionation services are specifically exempt from the MPPs.<sup>126</sup> Accordingly, for these products and services, an open approach to market is not strictly required.

**5.11** As the NBA's procurement of DBP included recombinant products that are not derived from plasma, the procurement was subject to the MPPs, and a tender process was required. Consistent with this, the NBA implemented a full tender process for its 2005–06 DBP procurement and a scaled procurement exercise in 2008–09 when it considered exercising the extension provisions in its existing contracts.

**5.12** The degree to which the NBA's procurement complied with the CPGs is set out in Table 5.3.

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<sup>125</sup> Finance, *Commonwealth Procurement Guidelines* (CGPs), 2008, p. 9.

<sup>126</sup> *ibid.*, p.40.

**Table 5.3**

**Compliance with CPGs for 2005–06 DBP procurement**

**Criterion: Procurement involved a suitable approach to the market that satisfied the CPG requirements to encourage competition and the choice of procurement process was supported through an approved business case.**

**This criterion was met.**

- An appropriate open approach to the market was taken in 2005. Consultation and market research was undertaken in tandem with developing the Request for Tender (RFT).

**ANAO comment**

- The NBA would benefit from documenting its procurement approach earlier in the process, for example through an approved business case or a procurement plan (also see below).

**Criterion: The NBA's procurement process was structured and supported by appropriate, timely and approved documentation including a procurement plan, request for tender document and an evaluation plan.**

**This criterion was largely met.**

- The NBA produced key procurement documents that contained most of the key features required by the Mandatory Procurement Procedures.

**ANAO comment**

- The NBA's procurement strategy (which included the risk management plan) and the tender evaluation plan were approved very late (at tender closing), significantly reducing their usefulness.
- The NBA included external experts in its tender evaluation working groups as well as its Tender Evaluation Committee. Better practice is for the latter to be comprised of officials from relevant agencies rather than to include external advisors.<sup>127</sup> In future procurements, broader stakeholder consultation may help minimise any need perceived by the NBA to include external experts on its Tender Evaluation Committees.
- For the Tender Evaluation Committee and working groups, the NBA managed the associated confidentiality and conflict of interest issues.

**Criterion: An approved evaluation report was on file and it demonstrated that the NBA followed a suitable procurement process. The NBA followed procedural procurement rules (for example, rejecting late tenders).**

**This criterion was largely met.**

- An approved tender evaluation report was on file and this generally reflected sound practice. The NBA followed procedural rules and undertook an appropriate comparative analysis of price over the life of the contract.

**ANAO comment**

- Decision-making would have been better supported by more transparency in the evaluation process. For example, a clearer structure could have been used for rating compliance of tender responses with requirements. Relative weightings given to tendered price and compliance with other tender requirements could have been made explicit.<sup>128</sup>
- In the absence of a formal risk plan having been implemented to manage the procurement risks, the NBA took steps to mitigate and eliminate individual risks as they emerged.

Source: ANAO analysis.

<sup>127</sup> Department of Finance and Deregulation, Guidance on the Mandatory Procurement Procedures, Financial Management Guidance No. 13, 2005, p.38

<sup>128</sup> Department of Finance and Deregulation, Procurement Policy Framework Frequently Asked Questions <[www.finance.gov.au/procurement/procurement-policy-and-guidance/procurement-policy-faqs.html](http://www.finance.gov.au/procurement/procurement-policy-and-guidance/procurement-policy-faqs.html)> [accessed 9 June 2011].

**5.13** Generally, the NBA's actions in procuring DBP in 2005–06 were appropriate and largely consistent with the CPGs. There would be benefit in the NBA more closely aligning its future blood product procurements with better practice by: completing and approving all key procurement documents in a timely manner; limiting the role of external experts to that of contributors to tender evaluations, not decision-makers; more transparently evaluating tenders by recording the rules for ratings in advance of evaluation and considering making evaluation weightings explicit in request for Tender (RFT) documents.

### **Extension of the contracts in 2008–09**

**5.14** The existing DBP contracts were due to expire on 30 June 2009, although they contained an option to extend the arrangements for up to two years. The Department of Finance and Deregulation (Finance), gives the following guidance on extending contracts:

If a contract includes an option to extend its period of operation, agencies may exercise the option to extend the contract, following a value for money assessment. This requires conducting a process to assess the comparative value of exercising the option compared to re-approaching the market.<sup>129</sup>

**5.15** In May 2008, the NBA issued a request for information (RFI) to determine the relative merit of extending the contracts or going to tender. In assessing the RFI responses, the NBA considered overseas prices, alternative providers and value for money. Based on its analysis, prior knowledge of the market, and indications that the existing contracts largely met end-user preferences, the NBA extended the contracts for two years.

**5.16** While the NBA had documented this process, including the main decisions, in general, execution of the process would have been strengthened by: more timely completion and approval of the procurement strategy; completion of internal research (such as legal advice); and active consultation with stakeholders.

### **Probity and regulatory compliance**

**5.17** In procurement activities of any scale, public sector agencies must act with probity and satisfy the technical requirements of the CPGs. These

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<sup>129</sup> *ibid.* [accessed 9 June 2011].

requirements support agencies to achieve fairness, transparency and value for money.

**5.18** The NBA demonstrated a satisfactory degree of probity in its procurement of DBP in both 2005–06 and 2008–09. Although its transparency and probity assurance would be improved by keeping more consolidated records on probity, the NBA satisfied the FMA regulatory requirements.

## Design of the Deed with Baxter

**5.19** The ANAO assessed the NBA's 2006 Deed with Baxter against the guidance material contained in the Department of Finance and Administration and ANAO Better Practice Guide, *Developing and Managing Contracts*, 2007 and the ANAO Better Practice Guide, *Public Sector Governance*, Guidance Paper No.7, *Cross-Agency Governance*, 2003.

**5.20** The contract contained the majority of the expected provisions, such as roles and responsibilities, deliverable specifications, performance indicators and payment details. The contract and variations had been properly executed, with signed copies readily accessible from the NBA's files. The Deed also reflected the majority of the specifications requested by expert stakeholders early in the procurement process.

**5.21** Notwithstanding these elements, future contractual arrangements could be strengthened by the inclusion of the following elements:

- a complete, pre-defined dispute resolution mechanism;
- provision for the NBA to formally review supplier performance at intervals, incorporating end-user feedback, and report this to the supplier;
- a complaints resolution mechanism that involves the NBA, enabling it to obtain direct knowledge of complaints, rather than relying on the supplier to report complaints;
- the names and details of the NBA and the provider organisation's agreement managers and other key contacts; and
- a framework for regular meetings—including a minimum frequency and the level of attendees to be involved.



## Ongoing management of the contract

**5.22** The ANAO examined how effectively the NBA managed the Baxter contract on a day-to-day basis, giving particular attention to communication, report monitoring and performance improvement.

**5.23** In general, the NBA's management of the Baxter contract was satisfactory. In particular, the NBA:

- was in regular communication with Baxter personnel;
- took appropriate steps to remind Baxter of, and enforce, contract provisions;
- pursued supplier performance issues raised by users in a timely manner;
- checked Baxter's monthly reports upon receipt<sup>130</sup>;
- checked invoices and made payments in a timely manner; and
- maintained a sound record of actions taken, including contract variations.

**5.24** The monthly reporting by Baxter was generally useful; it largely met the contract reporting requirements and addressed the KPIs.<sup>131</sup> This enabled the NBA to identify performance issues requiring close management, such as maintenance of Baxter's agreed 'In Country Reserve' for particular products.

**5.25** While the NBA's administration of the Baxter contract was satisfactory, useful enhancements to the contractual relationship with Baxter or future suppliers would include:

- seeking direct end-user feedback on a regular, scheduled basis on supplier performance, NBA contract management performance and satisfaction with products and ancillary items; and
- implementing a relationship management protocol. The previous (2003) Deed between Baxter and the Department of Health and Ageing

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<sup>130</sup> There is limited checking that the goods delivered meet contract requirements before the monthly invoices are approved.

<sup>131</sup> The detail of reporting against each KPI varied. KPIs that were not reported in the detail in monthly reports were subject to periodic audits by the NBA—Goods Ordering and Receipt Verification audits.

(DoHA) included the following relationship principles which could be useful in this respect.<sup>132 133</sup>

#### **4 Relationship of the Parties**

##### **Principles guiding the relationship of the parties**

- 4.1 The Parties recognise that their mutual objectives under this Deed are consistent and, in order to maximise achievement of the objectives of this Deed, intend to act towards each other on the basis of the following principles:
- 4.1.1 Recognising the importance of maintaining an open and communicative relationship;
  - 4.1.2 Identifying, managing and mitigating risks within their control;
  - 4.1.3 Conducting themselves in a spirit of co-operation and good faith; and
  - 4.1.4 Being flexible and realistic in managing the Deed and complying in full with procedures established under the Deed.

**5.26** During the audit, the NBA reviewed Baxter's contract performance from 2006 to 2010. This would be a useful activity to implement as a more routine element of the NBA's broader procurement functions.

### **Improving contract management**

**5.27** Since the NBA's establishment in 2003, it has progressively implemented useful initiatives to help it operate as an informed contract manager. These initiatives include:

- an annual Blood Product Suppliers Forum that is attended by both current and potential suppliers. Supplier feedback has been positive;
- an annual Professional and Community Advisory Forum; and
- the Collaboration of National Plasma Product Supply Planners.

**5.28** The NBA has also developed internal guidance documents to assist its staff in managing contracts for commercial blood products. Taken together, these contain useful material that reflects government policy:

- Key Business Process (KBP) 3—Tendering and Contract Negotiation—Blood Products and Services;
- KBP 4—Contract Management and Review; and
- Contract Management Guidelines.

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<sup>132</sup> Defined Blood Products Deed, Commonwealth of Australia and Baxter Healthcare Pty Ltd, 2003–2006.

<sup>133</sup> The NBA advised that these suggestions had been incorporated into its new contracts resulting from the DBP tender process.

**5.29** There are opportunities for the NBA to build on these activities to improve its contract management in two particular areas: risk management and stakeholder consultation. Specifically, the NBA's risk planning would be strengthened by more timely completion and approval of plans, as well as monitoring and reporting against these.

**5.30** The NBA is a manager of significant cost contracts—the contract with Baxter amounted to expenditure of \$90 million in 2009–10. Given this context, demonstrating value for money in its contracting involves the NBA obtaining a competitive price for products, as well as providing assurance of end-user satisfaction with supply. While the NBA carried out external consultation for the procurement process in 2005, and to a lesser extent in 2008, it did not obtain regular feedback on the contract effectiveness. A more informed, streamlined approach to procurement processes and options could be achieved by the NBA: proactively seeking and analysing user feedback on a more regular basis; and allowing additional time up-front for informal consultation.

## 6. Monitoring Performance

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*This chapter assesses the NBA's approach to monitoring and reporting its performance, and the data capacity supporting these activities.*

### Introduction

**6.1** In accordance with the Australian Government's Outcomes and Programs Reporting Framework, each public sector agency must assess, and report to the Parliament, the progress and performance of programs for which it has responsibility. Underpinning this process is the collection, analysis and reporting of relevant performance information, including a combination of quantitative and qualitative data designed to assist management decision-making and the accurate reporting of agency achievements.

**6.2** Performance information is most effective when it provides a balanced coverage of the agency's outcomes, programs and deliverables through a specified and concise set of performance indicators. These indicators should be clearly defined and easy to understand, achievable, and enable the comparison of performance against targets over time.

**6.3** To assess the effectiveness of the NBA's performance monitoring and reporting, the ANAO examined the agency's:

- outcomes and programs structure;
- key performance indicators;
- program deliverables;
- performance reporting; and
- data collection and management.

### Outcomes and programs structure

**6.4** The key elements of the Australian Government's Outcomes and Programs Framework are:

- specification of the outcomes the Government is seeking to achieve in the community;
- identification of programs and their associated deliverables (the goods and services produced and delivered by a program);

- establishment of a performance management regime that enables the measurement and assessment of the contribution of programs to their respective outcomes; and
- annual performance reporting by departments on their delivery of programs.

**6.5** This framework replaced the Outcomes and Outputs Framework that was in place from 1999 to 2010. As part of its transition to the new arrangements, the NBA updated its Outcome/Program structure in the 2009–10 Portfolio Budget Statements (PBS).

**6.6** In line with current requirements, the NBA’s 2010–11 PBS identifies the agency’s outcome and programs structure. This consists of a single outcome and one program, Program 1.1 *National Blood Agreement Management*, under which there are three Major Activities and a range of deliverables (Table 6.1).

**Table 6.1**

**NBA outcome and program structure**

<b>NBA Outcome</b>		
Access to a secure supply of safe and affordable blood products, including through national supply arrangements and coordination of best practice standards within agreed funding policies under the national blood arrangements.		
<b>Program 1.1</b>		
National Blood Agreement Management		
<b>Program Objectives</b>		
Program 1.1 aims to:		
Ensure the secure supply of all required blood and blood products through effective procurement and management of product availability	Implement blood sector policy and systems to reduce risk and improve performance	Facilitate appropriate blood management and safe use of blood products for all patients
<b>Major Activities</b>		
Program 1.1 deliverables fall under three Major Activities that relate to the program objectives:		
Secure the supply of blood and blood products	Risk management and sector performance improvement	Appropriate patient blood management and safe use of blood and blood products
<b>Deliverables</b>		
NBA identifies ‘quality’ and ‘quantity’ deliverables to meet Program 1.1 objectives (also see Figure 6.3)		

Source: Health and Ageing Portfolio Budget Statements 2010–11, pp. 693–701.

6.7 This structure provides an appropriate foundation for the NBA to measure its performance in delivering Program 1.1 and to demonstrate contributions to the specified outcome. The various components of the performance framework are also consistent with the agency's functions as specified in the NBA Act and the policy parameters of the National Blood Agreement.

## Key Performance Indicators

6.8 Agencies measure and report the impact (or effectiveness) of their programs through the collection of information against a set of suitably tailored Key Performance Indicators. Realistic, useful and relevant indicators assist internal managers, the Parliament and the public to understand the value of a program and, in particular, its impact and contribution to the planned outcome.

6.9 The ANAO assessed whether the NBA's (2010–11) performance framework contained appropriate performance measures and sufficient detail to allow stakeholders to identify the contribution of Program 1.1 and associated major activities to its stated outcome.

### Key Performance Indicators identified by the NBA

6.10 To be well placed in assessing the contribution of its programs to long-term outcomes, it is important for the NBA to identify the best effectiveness indicators to report against. The Department of Finance and Deregulation emphasises the importance of performance indicators and suggests indicators for particular types of programs (for example an *Assisting program* and an *Advising or Informing program*).<sup>134</sup> Examples relevant to the NBA would include:

- *Assisting program*—through contracts with third parties, the NBA provides blood products and services to assist individuals; and
- *Advising/informing program*—the NBA provides advice to government and technical guidelines to health professionals on the appropriate use of blood and blood products to improve their decisions and choices.

6.11 Suitable performance indicators for these programs or activities would usually capture and track the timely delivery of goods and services, client

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<sup>134</sup> Department of Finance and Deregulation, Portfolio Budget Statements Constructors Kit, 2009–10.

satisfaction with the delivery of goods and services, or the acceptance and take-up of advice by specific target groups.

**6.12** The Key Performance Indicators for Program 1.1 *National Blood Agreement Management* consist of both quantitative and qualitative indicators which align with the NBA's three major activities (Table 6.2).

**Table 6.2**

**Key Performance Indicators identified for Program 1.1**

Major activity	Qualitative Key Performance Indicators	Quantitative Key Performance Indicators
<b>Secure the supply of blood and blood products</b>	Management and coordination of Australia's blood supply in accordance with the National Blood Agreement between the Australian Government and state and territory governments.	Percentage of administrative costs as a proportion of the national supply plan budget, under the National Blood Agreement.  Variance between actual and NBA estimated total demand for supply of products.
<b>Risk management and sector performance improvement</b>	Management of the National Blood Supply Contingency Plan.	Number of days the National Blood Supply Plan is activated for plasma and recombinant products.
<b>Appropriate patient blood management and safe use of blood and blood products</b>	Quality advice provided to guide promotion of safe, high quality patient blood management and use of blood and blood related products.	Number of downloads of guidelines and criteria from website.

Source: *Health and Ageing Portfolio Budget Statements 2010–11*, p. 699.

**6.13** The NBA's current indicators (as represented in its 2010–11 Portfolio Budget Statements) are useful, but could be improved to better represent the overall effectiveness of the NBA's program and the impact of its more strategic rationale.<sup>135</sup>

**6.14** Overall reporting of the NBA's program and outcome effectiveness would be strengthened, for example, by seeking broader feedback about: client satisfaction with the delivery of goods and services and the acceptance and take-up of advice by specific target groups; and developing indicators that reflect a more representative cross-section of the NBA's program. A greater emphasis on indicators that address program cost-effectiveness and value for money would also improve the higher level focus of the NBA's performance framework and performance reporting. These matters are explained below and later in the chapter.

<sup>135</sup> *Health and Ageing Portfolio Budget Statements 2010–11*, p. 693.

### *Qualitative indicators—capturing feed-back from stakeholders*

**6.15** When determining program effectiveness, it is useful to take into account the perspectives of a range of stakeholders or to seek their views. While stakeholders are likely to make judgements based on individual perceptions, collectively, attitudes can have a significant impact on the success of a program and its contribution to broader outcomes.

**6.16** Each of the NBA's quality performance indicators (Table 6.2) has a key performance target of obtaining a 'high level of satisfaction' from its most significant client—the Jurisdictional Blood Committee (JBC).<sup>136</sup> Views on the NBA's performance are obtained through a survey of JBC members and, while subjective, this provides some measure of the impact of the NBA's program and major activities.

**6.17** The NBA could find it beneficial to assimilate qualitative information on the broader impact or effectiveness of the NBA's program and activities on the blood sector. For example, carefully designed surveys targeted at other stakeholders, such as clinicians, transfusion nurses, laboratory managers and donors, would facilitate the collection of specific information to assist the NBA and the JBC in aspects of supply planning, policy development and the identification of areas for service improvement or efficiency initiatives.

### *Quantitative indicators—developing more representative indicators*

**6.18** NBA measures of effectiveness include the quantitative indicators: 'percentage of administration costs as a proportion of the national supply plan budget, under the National Blood Agreement'; and 'variance between actual and NBA estimated total demand for supply of products'. While these are valuable indicators, they are more relevant to assessing the efficiency of the NBA (also see the following section of this audit—Program deliverables) rather than the impact of Program 1.1.

## **Program deliverables**

**6.19** Deliverables are the goods and services produced and delivered by a program in meeting its objective. Each agency is required to report on the deliverables in their Annual Reports. To allow for consistent estimation over time, deliverables should be measurable and quantifiable units or activities.

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<sup>136</sup> The JBC represents the Australian, state and territory governments' positions on blood policy, supply planning, distribution and funding, and oversees NBA activities (also see Chapters 2 and 3).



This is best achieved by setting quantity, quality and cost/price indicators, and reporting against these, recognising that:

- quantity is typically the number of products and/or services that are produced for a given cost;
- quality relates to attributes such as timeliness, coverage, accuracy and conformity to specifications. Although more difficult to measure, criteria such as client satisfaction and public perception can also be used to assess quality; and
- program cost performance information allows judgements to be made about the cost of administration and to ascertain whether there are more efficient ways of achieving program objectives.

**6.20** The ANAO examined whether the NBA had identified measurable deliverables with adequate program coverage.

### The NBA's deliverables

**6.21** The NBA identifies deliverables against each of its three major activities (Table 6.3).

**Table 6.3**

#### Deliverables identified for the NBA's Program 1.1

Major activity	NBA qualitative deliverable	NBA quantitative deliverable
<b>Secure the supply of blood and blood products</b>	Contract(s) completed for the importation of intravenous immunoglobulin.	Fourteen blood supply contracts managed.
<b>Risk management and sector performance improvement</b>	Implement new product levels for national reserve inventories and new supplier contract arrangements.	Greater than or equal to 95 per cent of recommendations from the Administrative Review of the Blood Arrangements, for which the NBA has responsibility, completed within timeframe.
<b>Appropriate patient blood management and safe use of blood and blood products</b>	Provide clinicians with evidence-based information on safe and appropriate blood management by releasing two elements of the National Health and Medical Research Council <i>Clinical Practice Guidelines for Patient Blood Management</i> .	Two National Health and Medical Research Council <i>Clinical Practice Guidelines for Patient Blood Management</i> published.

Source: Health and Ageing Portfolio Budget Statements 2010–11, pp. 697–8.

**6.22** The NBA's qualitative deliverables tend to focus on timeliness—the dates that significant contracts will become operational or guidelines will become available. Quantitative deliverables include the number of blood supply contracts that the NBA manages and the number of guidelines released as key quantifiable deliverables.

**6.23** Inclusion of indicators that encourage the collection of information about the quality or acceptance (by key stakeholders) of the deliverables, and whether they represent good value for money, could provide valuable insight

into the usefulness of particular activities and deliverables, and hence how these contribute to the program's effectiveness and efficiency.

## Performance reporting

**6.24** Performance information is used by agencies for both external and internal reporting. External reports, particularly Annual Reports, focus on the contribution of programs to the achievement of outcomes and programs, including through the delivery of goods and services to the community or specific target groups.

**6.25** Effective annual reporting is characterised by accuracy and transparency, and should include a balanced coverage of the key elements, achievements and shortcomings encountered over the previous year.

**6.26** The ANAO examined the NBA's annual reporting for key deliverables of Program 1.1, *National Blood Agreement Management*, and how the agency:

- measured the efficiency of the NBA's program delivery;
- estimated value for money in the supply of blood and blood products; and
- progressed recent initiatives to assist the more efficient use of blood and blood products.

### Measuring the efficiency of program delivery

**6.27** Data on the cost of the resources required to administer a program, in conjunction with performance information such as the quantity of products and the quality of services delivered, can be used to provide a picture of the efficiency of operations.

**6.28** To track the efficiency of implementing Program 1.1 'National Blood Agreement Management' over time, the NBA measures the percentage of its administration costs as a proportion of the national blood supply plan budget. A target is set at 'less than 1.4 per cent'. In 2009–10, funding for the supply of blood and blood products was \$878 million and departmental expenditure (administration costs) totalled \$9.2 million, equating to 1.02 per cent, which is within the NBA's target.<sup>137</sup>

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<sup>137</sup> Figures taken from the NBA Annual Report 2009–10, pp. 21–22 and 28.

**6.29** While this is a useful measure to track the efficiency of the NBA internal operations over time, the delivery of the national blood supply program is also influenced by the broader blood sector. The quality of services provided through NBA-managed contracts and various governance arrangements are also subject to performance scrutiny and contribute to overall blood sector efficiency.

**6.30** Several reviews have examined elements of the blood sector and blood supply arrangements since 2001, making recommendations for sector-wide improvements, including more efficient practices. Given governments' interest in the efficiency of the Australian blood sector, there would be benefit in the NBA (in collaboration with JBC, DoHA and the broader blood sector), identifying mechanisms to quantify the impact of such efficiency improvements, so that the actual efficiencies achieved can be reported in a readily tangible form.

### **Estimating value for money in the supply of blood and blood products**

**6.31** The supply of blood and blood products is largely accomplished by a series of purchaser-provider contracts established by the NBA. Value for money is the core principle underpinning Australian Government procurement. In a procurement process this principle requires a comparative analysis of all the relevant costs and benefits of each proposal throughout the whole procurement cycle.<sup>138</sup>

**6.32** However, value for money is a difficult principle to implement across all facets of the NBA's purchasing environment, particularly given the monopoly provider arrangement with the not-for-profit organisation, ARCBS, for fresh blood products and services. To clarify expectations, the Minister for Health and Ageing set out the Government's expectations for value for money (see Chapter 4, Table 4.3). Steps taken in the past two years by the NBA, governments and the ARCBS, including a KPMG business study, have also focused more on the achievement of business efficiencies within the ARCBS. A large body of improvements have been made and the remainder are underway.

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<sup>138</sup> Department of Finance and Deregulation, *Commonwealth Procurement Guidelines*, Financial Management Guidance No. 1, Canberra, December 2008.

**6.33** The NBA's 2008–09 and 2009–10 Annual Reports provide information on the general trends in the areas targeted by its Program 1.1, and draws attention to the factors underpinning the high rate of growth in Australia's expenditure on blood and blood products, including:

- increasing demand being driven by an ageing population and the increasing use of intravenous immunoglobulin;
- the increasing cost of fresh blood products;
- the introduction of government approved safety/quality measures such as universal leucodepletion and bacterial testing of platelets; and
- the introduction of recombinant products.<sup>139</sup>

**6.34** Overall, this contextual information illustrates the broad environment in which the NBA operates and the reasons behind Australia's increasing blood supply expenditure. The NBA also highlights areas where it considers it has been successful in achieving value for money and where the agency has had limited opportunity to influence value for money. The agency's analysis concentrates on cost/price trends, notably:

- the achievement of savings on imported plasma and recombinant product prices;
- increased funding to the Australian Red Cross Blood Service (ARCBS) to supply fresh blood components. In the seven years to 2009–10, annual funding for fresh blood and plasma collections has increased from \$248 million to \$456 million; and
- government approved safety/quality measures costing an additional \$63 million a year.<sup>140</sup>

**6.35** While this type of cost data assists in understanding the efficiency of product and service delivery, assessing value for money also requires consideration of the quality of the services provided over time.<sup>141</sup>

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<sup>139</sup> NBA Annual Reports 2008–09 and 2009–10.

<sup>140</sup> NBA Annual Report 2009–10, p. 35.

<sup>141</sup> Commonwealth of Australia, *Building the Education Revolution Implementation Taskforce: Interim Report*, August 2010. This report considered the wider public perceived value for money and concluded there are three criteria in assessing whether a service or product represents value for money: quality, time and cost.

### *Quality metrics for safety measures*

**6.36** Australia has an altruistic system for the donation of blood that depends on public confidence. Users of blood and blood products in Australia rely on it being one of the safest systems in the world. Maintaining this level of confidence and safety requires ongoing evaluation of the screening and testing methods and the introduction of new approaches to blood collection and processing within the blood sector.

**6.37** However, safety measures also have a cost. The implementation of government approved safety measures (such as universal leucodepletion of red cells and platelets, and bacterial testing of platelets) resulted in an average increase of 4.3 per cent a year in the NBA's expenditure on fresh blood supplies.<sup>142</sup> The assessment of value for money therefore requires a balanced consideration of the costs and benefits.

**6.38** To properly assess value for money in relation to safety measures, the NBA will need to create and use quality metrics. The concept of quality is subjective, so it will be necessary for the NBA to obtain and consider feedback on stakeholder satisfaction across a range of stakeholders (blood donors, blood users, health professionals and governments) to better inform the NBA's value for money calculations and identify both positive and negative outcomes.

**6.39** Overall, the NBA would strengthen its calculation and reporting of value for money by including:

- trends in key quality measures for its major contracts, including for the ARCBS Deed of Agreement; and
- implementing a nationally agreed set of quality metrics for safety measures introduced by government.<sup>143</sup>

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<sup>142</sup> NBA Annual Report, 2008–09, p. 31.

<sup>143</sup> During the audit, the NBA reported to the ANAO that a proposed set of performance metrics for quality measures were part of the Patient Blood Management Program approved by the JBC in December 2010.

## **Progressing initiatives to assist the more efficient use of blood and blood products**

**6.40** Improving value for money and efficiency within the blood sector is also dependent on the uptake of initiatives to: address inappropriate use of blood products; reduce product wastage and promote best practice in the blood sector.

**6.41** As signatories to the National Blood Agreement, the Australian, state and territory governments are responsible for:

[fostering] the development and implementation of best practice planning and management of systems for blood products and blood related products within each jurisdiction, to promote efficient use and minimisation of wastage.

**6.42** Progress against this is presented under the NBA's third strategic direction 'Appropriate patient blood management and safe use of blood and blood products'.<sup>144</sup>

**6.43** The NBA and the JBC are progressing several initiatives to minimise demand increases, reduce wastage and promote the use of products in accordance with best practice standards. Examples include:

- Clinical Practice Guidelines: to encourage appropriate use of blood products by Australian Health Providers;
- National Haemovigilance Program: to monitor the use of specific blood products used in bleeding disorders, to assist in future supply planning, improve use and clinical outcomes; and
- data system developments: to monitor distribution, inventory, usage patterns and wastage of blood products, to inform supply planning and efficiency measures.

**6.44** The NBA has used a range of activities to engage pathology services, hospitals and clinicians in the development and implementation of such initiatives.<sup>145</sup> These stakeholders have a crucial role in shaping the blood sector—including changing behaviours in the use of blood products, and the facilitation of more rigorous monitoring of use and wastage. As many of the strategies take many years to develop, it is important that stakeholders are

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<sup>144</sup> NBA Annual Reports 2008–09, pp. 70–83; and 2009–10, pp. 52–62.

<sup>145</sup> Including working groups and committees, public consultations, newsletters and the NBA website.

kept well informed of progress at each stage and are consulted at regular intervals during development and implementation. This will help to ensure that potential problems or difficulties are detected and responded to early.

**6.45** Greater benefit could also be gained from the NBA taking a more structured approach to consultation and evaluation. For example, the uptake of the Clinical Practice Guidelines has the potential to reduce wastage and improve appropriate use of blood and blood products. The development of an evaluation strategy would assist the NBA in establishing mechanisms to track and measure the extent of uptake and use of the Guidelines and their impact on blood use trends and wastage.

## Recommendation No.5

**6.46** To strengthen the NBA's measurement and reporting of program effectiveness, including value for money, the ANAO recommends that the NBA:

- establish mechanisms to better determine the impact of new blood safety measures on patient outcomes and blood sector efficiencies; and
- develop clear strategies to determine the impact of governments' initiatives to promote appropriate use of blood and blood products (including Clinical Practice Guidelines), for example evaluation strategies.

NBA response: *Agreed*

## Data collection and management

**6.47** For the blood sector, the collection and analysis of accurate, complete and relevant data is important for a range of essential business functions, for example, to:

- inform supply planning and budget development;
- measure progress against program objectives to determine whether broader outcomes are being met; and
- provide information on usage trends, wastage and issues affecting the blood supply.

**6.48** The role of NBA in developing and fostering data capability in the blood sector has been advocated through various avenues, including the:

- Stephen Review (2001), which included a recommendation to implement a national information management and reporting system to monitor product issue and use across the Australian blood sector.<sup>146</sup>
- National Blood Agreement (2002), which specifies that the NBA is to undertake or facilitate national information management, benchmarking and cost and performance evaluation for the national blood supply.<sup>147</sup>
- Webster Review (2009), which recommended the NBA progress the implementation of the Sector Information Management and Data Strategy (SIMDS) and identified the need for strategic high level data and analysis;<sup>148</sup> and more generally
- the NBA Act—to liaise with and gather information from governments, supplies and others about matters related to blood products and services.

**6.49** The ANAO examined the NBA's progress in establishing a national system for data and information to support it in carrying out government policy objectives and its functions under the NBA Act.

## **The data environment**

**6.50** The NBA is reliant on data from the blood sector to inform its key operations and decision making, especially in the areas of supply planning, funding and policy evaluation. However, the collection and analysis of information at a national level is not yet supported by a suitable national data set.

**6.51** Information and data management across the various jurisdictions is complex, and the systems numerous and disparate. Most systems were designed to meet the data needs of individual blood sector entities (hospitals, laboratories, product suppliers, and each level of government) and developing interfaces for data transfer and integration can be costly and difficult. Considerable challenges therefore exist to establish systems across

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<sup>146</sup> *Review of the Australian Blood Banking and Plasma Product Sector*, March 2001, p. 99.

<sup>147</sup> op. cit., *National Blood Agreement 2002*, p. 8.

<sup>148</sup> Department of Health and Ageing (DoHA), *Administrative Review of the National Blood Arrangements*, September 2009.



jurisdictions, including agreement on national data sets, system design and integration, reporting specifications and funding priorities.

### **Systems development for national data collection**

**6.52** Since its establishment in 2003, the NBA has put considerable effort into developing systems to address national data needs. Although the success of these efforts has been variable, and the timeframes often prolonged, the agency is gradually strengthening its position in gaining access to data that usefully informs its key business decisions.

**6.53** The NBA commented that contract management and supply management systems had taken precedent over the development of national data systems. Notwithstanding this, the NBA's early approach to system development would have benefitted from greater technical support, strategic planning and priority. Early development of system encountered delays as data needs were reviewed and systems re-defined or re-developed (see Table 6.4 Case Study).

## Table 6.4

### Case study: development of the Integrated Data Management System

The following is an account of the development of the Integrated Data Management System (IDMS) from 2005 to early 2011

**Contracting:** In August 2005, the NBA engaged consultants to assist the NBA to release an Request for Tender (RFT) to procure an ICT services vendor for the development and implementation of an ICT system (which was subsequently named IDMS) to provide an integrated contract management system that contained all information relevant to the National Supply Plan and Budget. The RFT was released in March 2006, with a contract signed in September 2006.

**Delays:** However, the NBA experienced issues with the design, build and implementation of the system, and as a result, the initial 'go live' date of June 2007 was not realised. The IDMS eventually entered production service in August 2008, although full functionality was not utilised until June 2010.

**Evaluation:** The NBA evaluated the issues arising from the implementation of IDMS and identified the following key shortcomings in the project:

- the development of the specifications and management of the project was conducted within a small group within the NBA with insufficient engagement with the wider organisation;
- the NBA failed to adequately resource the project with the management of the project undertaken by those with business expertise, rather than ICT specific project management expertise and an insufficient quantity of resources dedicated to the project;
- the NBA failed to adequately manage the vendor and de-emphasised reporting (to enable the contractor to develop the system) despite the ongoing communication issues and milestone slippage of the vendor; and
- the task of data migration was under-estimated by both the vendor and the NBA and data cleansing and reconciliation activities are still being completed at present.

**Remedial action:** In recognition of these issues, the NBA restructure of July 2009 created a dedicated ICT team (iBlood) staffed with ICT professionals to manage all NBA ICT systems and projects. In the ensuing 12 month period, this team resolved the majority of outstanding issues with IDMS through the introduction of two new builds and deployed the system across both of the supply management teams within the organisation.

**System expenditure:** Since the establishment of the contract on 18 September 2006, \$3.5 million has been expended on the development, maintenance, ongoing builds of the system and associated software licences. The original RFT response for the system build was \$1 080 965. The NBA anticipated additional expenditure on IDMS during 2010–11 of around \$350 000.

**System functionality:** The reporting functionality in IDMS was curtailed in late 2008 when it was acknowledged that this functionality was not going to deliver the data expectations of the organisation. Further work was halted while the outstanding issues in IDMS were resolved and in November 2009 work commenced on a Data Warehouse (known as Big Red) that over time will provide centralised business intelligence and reporting system for all NBA ICT systems. Work to date on Big Red has focussed on data marts drawn from IDMS data sets, however, work is now underway to integrate data sourced from ABDR and ORBS (now BloodNet).

Source: Compiled from NBA information.

**6.54** Recognising the limitations of data readily available to the NBA and across the broader blood sector, in August 2008, the JBC endorsed a Sector Information Management and Data Strategy (SIMDS). The SIMDS was intended to 'enable NBA to provide data on performance measures for the Australian Blood Sector'. Among other things, the SIMDS provided a snapshot of the proposed functionality (or contribution) of the various data systems to the envisaged national integration of data (see Table 6.5).

Table 6.5

## Proposed contribution of data by product type to blood supply function

Blood supply function	Product type			
	Fresh blood	Clotting factors	IVlg	Other blood products
Donor management	Supplier system	N/A	N/A	N/A
Quality	Supplier systems			
Supplier Inventory	ORBS (subsequently became BloodNet)			
Supplier Wastage	IDMS			
Orders by Approved Health Providers (AHPs)	ORBS	ABDR	NIMS	ORBS
Authorisation	N/A			N/A
Inventory of and receipt by AHP	ORBS			
Fate of Product (DRG/Wastage)	ORBS	ABDR	ORBS	ORBS
Outcome identifiers for linkage	ORBS			
Outcome (outcome captured)	N/A	ABDR	NIMS	N/A
Reporting (operational and performance)	BIG RED			
Supplier payments	IDMS			
Contract performance	IDMS			
Jurisdictional payments	IDMS			
Supply plan performance	IDMS			
End user interface	blood.gov.au and 13 000 BLOOD (for support)			

Source: NBA Board Meeting 35, item number 3.1, 9 April 2010, p. 8.

## Notes:

Australian Bleeding Disorder Registry (ABDR)	Blood sector database recording clinical information for the treatment of people with bleeding disorders.
Big Red	BigRed is a business intelligence tool that will enable the NBA to easily synthesise, analyse and report data drawn from multiple systems.
BloodNet	BloodNet is designed to link between hospital pathology systems and the various systems in use by suppliers.
Integrated Data Management System (IDMS)	Internal NBA business data collection and management system for supplier and jurisdictions payments and supply plan performance.
National Immunoglobulin Management System (NIMS)	Blood sector data system for the ordering, receipting and capture of information about the use of IVlg.
Ordering Receipting Blood System (ORBS)—now BloodNet	Blood sector ordering, receipting and verification data system that acquits blood supplier invoices against known orders and deliveries. ORBS was incorporated into BloodNet in 2011.

6.55 Since 2009, the NBA has placed a greater focus on developing data capacity in line with the JBC-endorsed SIMDS. Progress of its data and information activities was reported regularly to the JBC and in the NBA’s 2009–10 Annual Report. Table 6.6 illustrates examples of activities undertaken by the NBA to strengthen its data capabilities and better inform its planning and operations.

**Table 6.6**

**Examples of activities undertaken to strengthen NBA and blood sector data capability**

Action/Involvement	Purpose and progress
Reviews (for example, the Crawford review in 2006)	To assess existing blood sector data and systems architecture, and develop options for more practical data management. <sup>149</sup>  <i>Progress: The reviews informed the SIMDS and ICT system developments.</i>
Redevelopment of the Australian Bleeding Disorders Registry (December 2008)	The system was designed to produce data for clinicians, patient representative groups and governments. It contains summaries of patient care records for people with bleeding disorders and is intended to promote enhanced quality of care.  <i>Progress: Work is still continuing to improve functionality to meet user expectations.</i>
Appointed a Chief Information Officer in 2009, and establishment of a dedicated ICT team	To strengthen its in-house ICT capabilities. Analysis of existing systems and data, to allow effective integration of systems.  <i>Progress: It was apparent that the NBA’s internal capability in ICT development and progression/re-evaluation of several initiatives had improved since 2009.</i>
Development of a draft set of performance measures for the blood sector (2009–10)	Designed to align with the existing national health performance matrix, with reporting at a national level, at the government level the performance measures are intended to capture effectiveness and management of the blood sector.  <i>Progress: The NBA is to release a public discussion paper in 2011.</i>
<i>Guide to the set of standard measures for the use of fresh blood components in Australia</i> , released for public consultation	To develop national standards for use by the blood sector that will enable consistent reporting using comparable data sets.  <i>Progress: Period of review concluded in June 2010. NBA is to review comments and prepare the initial version of the guide in 2011.</i>

Source: Compiled by the ANAO from various public and internal NBA documents, and interviews with NBA.

Note: This table is not all-inclusive.

<sup>149</sup> NBA Information/Knowledge Infrastructure Report, p.3.

**6.56** The NBA, in conjunction with the JBC, has demonstrated progress in recent approaches to address national data needs. Reforms in this area, however, carry significant risk because of the national focus required and the uncertainty of consensus and uptake of national systems by all states and territories. The need for robust data to support policy development, program implementation and analysis of performance is likely to increase as expenditure on the blood supply rises.

**6.57** Managing these risks will be an important step in moving towards a blood sector in which efficiency and effectiveness of government policies, and particularly blood sector reforms, can be measured.

**6.58** The NBA assesses its program efficiency through various analyses of cost data. Demonstrating and ensuring value for money in its blood supply functions requires additional information on the quality of the services and the impact of government measures to improve the use of blood products and reduce wastage over time. The recently developed ordering, receipting blood system, for example, is intended to facilitate better supply planning from a demand perspective; increase traceability of blood and blood products; and improve record keeping (see Appendix 7 Case Study).

**6.59** Further development of national systems and data sets should help to improve blood sector transparency and better inform the NBA's performance monitoring, supply planning and value for money across the range of NBA's functional responsibilities.

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Ian McPhee  
Auditor-General

Canberra ACT  
12 October 2011



# Appendices





## Appendix 1: Agency responses

### National Blood Authority response



Mr Matt Cahill  
Group Executive Director  
Performance Audit Services Group  
Australian National Audit Office  
19 National Circuit  
Barton ACT 2600

Dear Mr Cahill

Thank you for the opportunity to comment on the s19 report of the audit on the National Blood Authority's Management of the National Blood Supply.

The National Blood Authority (NBA) welcomes the findings of the audit that the NBA has established organisational structures and processes which allow us to carry out our governance responsibilities, play an effective central role in the national coordination of the blood supply and advance the efficiency and effectiveness of the sector. The audit has provided a good summary of the complex policy, historical context and multi-jurisdictional environment in which the NBA operates and the challenges that these bring to a small agency.

Through our operations and consistent with the agreed priorities of governments, the NBA will continue to seek to support a balanced approach to all primary policy objectives of the National Blood Agreement, namely to:

- (a) provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia; and
- (b) promote safe, high quality management and use of blood products, blood related products and blood related services in Australia

The NBA agrees to the five recommendations within the report. Work to implement recommendations 3, 4 and 5 has progressed during the audit and remains an ongoing focus.

Please accept my thanks for the professional and constructive approach that yourself, Mr Lack, Ms Geue and Ms Das brought to the audit.

Yours sincerely

A handwritten signature in black ink that reads "Steph Gunn".

Stephanie Gunn  
Ag General Manager

20/11/11


# Department of Health and Ageing response



Australian Government  
Department of Health and Ageing

SECRETARY

Mr Matt Cahill  
Group Executive Director  
Performance Audit Services Group  
Australian National Audit Office  
GPO Box 707  
CANBERRA ACT 2601

  
Dear Mr Cahill

PERFORMANCE AUDIT: NATIONAL BLOOD AUTHORITY'S MANAGEMENT OF  
THE NATIONAL BLOOD SUPPLY


Thank you for your letter of 22 August 2011 providing the Department of Health and Ageing with the opportunity to comment on the proposed report of the performance audit of the National Blood Authority's Management of the National Blood Supply.

The Department's formal response for inclusion in the summary is as follows:

Managing the supply of blood and blood products is a complex area particularly given the diversity of stakeholders and the shared funding arrangements between the Commonwealth and states/territories. The Department notes that there are a number of recommendations for which the NBA does not have sole responsibility and depend on co-operation of the states/territories and the public/private health sectors.

I look forward to receiving the final report and advice regarding the timing of the tabling of the report in Parliament.

Yours sincerely

  
David Learmonth  
Acting Secretary

19 September 2011

## Baxter Healthcare Pty. Limited response

Baxter Healthcare Pty. Limited  
 A.B.N. 45 000 302 781  
 Postal Address:  
 P.O. Box 88, Toongabie,  
 N.S.W. Australia 2146  
 1 Baxter Drive, Old Toongabie,  
 N.S.W. Australia 2146

Telephone: 02 9646 1111  
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19 September 2011

Matt Cahill  
 Group Executive Director  
 Performance Audit Services Group  
 Australian National Audit Office  
 19 National Circuit  
 Barton ACT

Via email: [mlex.qeue@anao.gov.au](mailto:mlex.qeue@anao.gov.au)

Dear Mr Cahill,

### AUDIT OF NATIONAL BLOOD AUTHORITY'S MANAGEMENT OF THE NATIONAL BLOOD SUPPLY

Thank you for the opportunity to respond to the Australian National Audit Office's performance audit of the National Blood Authority (NBA) and its management of the national blood supply (Audit).

We wish to comment on a number of points contained in the proposed Audit report.

#### 1. Compliance with CPGs for 2005-06 DBP procurement (Table 5.3) – Use of External Experts.

Baxter notes that the proposed Audit report refers to the technical requirements of the CPGs supporting agencies in achieving fairness, transparency and value for money. Baxter believes that the procurement process could be strengthened by the NBA adopting a more structured approach to its use of external experts. Specifically, Baxter is not aware that the NBA in using external experts to advise it on the procurement and process and evaluation of tenders has a process to select members who:

- are different from the members who advised on the previous DBP tender (to ensure rotation of members);
- are representative of key stakeholder groups; and
- subject to confidentiality requirements, engage with their individual constituencies to obtain their views on key issues and principles.

In particular, a number of external advisors were used both in the 2005-06 and the 2010-11 DBP procurement processes. This enhances the risk that there will be a myopic approach to the tender. A more structured approach to the selection and use of the external expert panel would ensure that there is balanced clinical involvement, which is particularly important given the unique situation with chronic users of the DBPs.

## 2. Transparency

The NBA indicated to Baxter that it wished to have pricing transparency following the 2010-11 DBP procurement process. This approach was not consistent with Baxter's global pricing policy, however Baxter was successfully able to achieve a change in internal policy to permit transparency of pricing.

As part of the Deed negotiations with the NBA following the 2010-11 DBP procurement process, the NBA sought transitional pricing from Baxter for its Factor VII products. Prior to providing the pricing, Baxter sought oral assurances from the NBA that the pricing would be transparent, which was confirmed. The expected and promised transparency in pricing was a material factor in Baxter's global pricing agreeing to allow submission of a substantially lower price for the transition period. Following Baxter's provision of transition pricing, the NBA advised that "the National Blood Authority's communication strategy at present does not include general publication of contract prices". This communication strategy adopted by the NBA is in breach of undertakings and representations made to Baxter during negotiations, and in addition runs contrary to the NBA's policy of transparency.

As a result of this, Baxter submitted a Freedom of Information request to obtain pricing on 21 June 2011. At the time of submission of this letter, it has not received details of pricing requested.

Yours sincerely,



David J Akroyd  
Area Managing Director ANZ

ANAO comment: Readers should note that the assessment of the DBP 2011 procurement process was not within the scope of the ANAO's audit of the NBA. Paragraphs 5.11 to 5.18 and Table 5.3 are relevant to the above response from Baxter Healthcare Pty. Limited.

## Appendix 2: List of blood products provided in Australia through NBA contracts

**Table A 2.1**

### Plasma and recombinant products 2009–10

Products supplied under the Plasma Products Agreement	Imported plasma blood products
Albumin products: <ul style="list-style-type: none"> <li>• Albumex 4</li> <li>• Albumex 20</li> </ul> Immunoglobulin products: <ul style="list-style-type: none"> <li>• Hyperimmune globulins</li> <li>• Intragam P</li> <li>• Rh (D) Immunoglobulin.</li> </ul>	Immunoglobulin products: <ul style="list-style-type: none"> <li>• Intravenous Immunoglobulin (three products)</li> </ul> Rare bleeding and blood disorder plasma products: <ul style="list-style-type: none"> <li>• Anti Inhibitor Coagulant Complex Concentrates</li> <li>• Protein C</li> <li>• FVII concentrate</li> <li>• WinRho</li> <li>• FXI</li> <li>• FXIII</li> </ul>
Imported recombinant products	
Rare bleeding and blood disorder recombinant products: <ul style="list-style-type: none"> <li>• rFVIIa</li> <li>• rFVIII (three products)</li> <li>• rFIX</li> </ul>	

Source: NBA Annual Report 2009–10, pp. 34, 212 and 213, adapted by the ANAO.

**Table A 2.2**

### Fresh blood components listed in the National Supply Plan 2009–10

Whole Blood	Whole Blood Clinical FFP
Whole Blood—Leucodepleted	Paediatric Whole Blood Clinical FFP (Set of 4)
Whole Blood Red Cell	Apheresis Clinical FFP
Whole Blood Red Cell—Leucodepleted	Whole Blood Cryoprecipitate
Whole Blood Red Cell—Buffy Coat Poor	Apheresis Cryoprecipitate
Whole Blood Paediatric Red Cell—Leucodepleted (Set of 4)	Whole Blood Cryo-depleted Plasma
Whole Blood Washed Red Cell	Apheresis Cryo-depleted Plasma
Whole Blood Washed Red Cell—Leucodepleted	Autologous from Blood Donors
Apheresis Red Cell—Leucodepleted	Directed donations complying with AHMAC Guidelines
Whole Blood Platelet	Therapeutic Venesections for Whole Blood for Discard
Whole Blood Platelet—Leucodepleted (Pool of 4)	Serum Eye Drops—Single Collection Unit
Whole Blood Platelet—Buffy Coat Poor (Pool of 4)	Granulocytes
Apheresis Platelet—Leucodepleted	
Paediatric Apheresis Platelet—Leucodepleted (Set of 4)	

## Appendix 3: NBA roles under the National Blood Agreement

25. The specific roles of the NBA in relation to the national blood supply, which must be exercised in accordance with the Commonwealth legislation including any policy principles issued to the NBA by the Ministerial Council through the Commonwealth Minister in accordance with that legislation, are:

(a) to liaise with and continuously gather information from State and Territory health authorities and other persons or bodies involved in the use of blood products or blood related products in relation to the demand for those products;

(b) in consultation with each Party, and for the approval of the Ministerial Council or the Jurisdictional Blood Committee, to undertake annual supply and production planning and budgeting in accordance with the process set out in Schedule 2;

(c) to use best endeavours to manage the national blood supply to provide a sufficient level of supply to meet the demand in all States and Territories National Blood Agreement Page 8 and to ensure that patients continue to access the blood products and blood related products their clinicians determine will best meet their needs so far as practicable in accordance with national best practice based on clinical guidelines. This clause does not preclude States and Territories from altering the range of blood products and blood related products that are prescribed and received in their jurisdiction;

(d) to negotiate, enter into, vary, administer and enforce funding and supply contracts with bodies involved in the collection, production and distribution of products for the purposes of the national blood supply (but in doing so, not to act directly as a supplier of blood products, blood related products or blood related services);

(e) to administer payments to suppliers under funding and supply contracts;

(f) based on its annual supply and production planning and budgeting, and on the funding and supply contracts with suppliers, to develop the national price list for products for the purpose of the joint funding arrangements for the national blood supply established under Part 5 and Schedule 3;

(g) to refer national blood supply change proposals to the Jurisdictional Blood Committee for consideration for evidence-based evaluation in accordance with clause 28 and Schedule 4;

(h) to administer provisions of the legislation establishing the NBA and other applicable legislation relevant to the administration or enforcement of funding and supply contracts;

(i) to establish and manage contingency and risk mitigation measures in relation to the national blood supply, including specific strategies developed in consultation with the Jurisdictional Blood Committee and approved by the Ministerial Council;

(j) to report annually, and on an ad hoc basis in relation to significant new developments, to the Ministerial Council and the Commonwealth Minister;

(k) to provide information and advice to the Jurisdictional Blood Committee, and through the Jurisdictional Blood Committee to the Ministerial Council;

(l) to liaise with, obtain information and advice from, and provide information and advice to, Commonwealth, State or Territory governments or government agencies, relevant non-government persons or bodies, and relevant international governments or other bodies, on matters relevant to the national blood supply;

(m) to monitor the national and international environment in which the Australian blood sector operates for new technological, clinical, risk or other developments that may impact on the national blood supply;

(n) under the direction of the Ministerial Council and the Jurisdictional Blood Committee, to facilitate and fund appropriate research, policy development or other action in relation to new developments by relevant government or non-government persons or bodies; and

(o) to undertake or facilitate national information management, benchmarking and cost and performance evaluation for the national blood supply

## Appendix 4: Reviews of the NBA and Australian blood sector from 2000–2010

The review Conducted/commissioned by	Purpose/significant outcomes
<p><b>2001: The Review of Australian Blood Banking and Plasma Product Sector (Stephen Review)</b> Established in 1999 by the then Commonwealth Minister for Health and Aged Care</p>	<p>Extensive review of the Australian blood sector, leading to substantial changes: Centralisation of management of the blood sector; Creation of the NBA; National Blood Agreement.</p>
<p><b>2005: The National Blood Authority Funding (Resource) Review</b> NBA internal review</p>	<p>An internal review of the NBA resources and capacity to meet legislative requirements.</p>
<p><b>2005: The Development of a Strategic Framework for the Jurisdictional Blood Committee (JBC)</b> Department of Health and Ageing (DoHA)/JBC</p>	<p>Lack of clarity about the roles and responsibilities of the various blood sector advisory bodies and their relationship to the JBC as the key policy and decision making body. Strategic policy matters were not formally identified and therefore not considered.</p>
<p><b>2006: Review of Australia's Plasma Fractionation Arrangements (the Flood Review)</b> DoHA</p>	<p>Determined that Australia should continue the arrangement whereby CSL hold a monopoly on fractionation in Australian plasma. Recommendations of the Review had implications on future work of the NBA, including a revision of the Distribution arrangements and the re-negotiation of the monopoly agreement with CSL in December 2009.</p>
<p><b>2008: Business Study of the Australian Red Cross Blood Service</b> NBA as per Deed of Agreement and AHMC requirement. Conducted by KPMG.</p>	<p>The final report of the Business Study was provided to NBA, JBC and AHMC. The ARCBS was presented with 35 recommendations to be implemented, which aimed to improve: financial governance arrangements, efficiency and effectiveness; financial and capital management; proposed funding model; and safety business cases.</p>
<p><b>2006–2009: Crawford Review (2006) and Lewis–Hughes Review (2009)</b> NBA</p>	<p>Both reviews focused on the highlighted need for a blood sector wide information management and data systems. The Crawford review focused on particular data projects/ issues that could influence the behavior of blood sector players. The Lewis-Hughes review was NBA reviewing its structure to facilitate inter alia a more integrated approach to data issues. A Sector Information Management and Data Strategy (SIMDS) was developed in 2008.</p>
<p><b>2009: Distribution Review (logistics Bureau)</b> NBA</p>	<p>First stage review of the supply chain for fractionated and recombinant products. The review examined the end-to-end supply chain to identify improvements.</p>
<p><b>2009: Administrative Review of the Australian Blood Sector (Webster Review)</b> DoHA as per National Blood Agreement requirement</p>	<p>The report emphasised the complex, time consuming and sometimes ambiguous nature of the multi-jurisdictional decision making and governance environment in which the National Blood Agreement operates. An implementation plan has been approved by AHMC. Aspects of the NBA's external governance arrangements and related responsibilities are currently subject to revision following the approval of the implementation plan.</p>

## Appendix 5: NBA and ARCBS protocols and joint arrangements status

### Development and current status of NBA and ARCBS protocol and joint arrangement under the 2006–09 Deed (and its 2010 and 2011 extensions).

Title	Type of Agreement	Progress	Status
Development and Management of the Strategic Capital Investment Plan (SCIP)	Joint Arrangement, not required under the Deed	Agreed at CEO meeting 6 August 2007 Signed 17 June 2009	Signed
Monitoring, review, payment and acquittal of approved projects under the change program funding pool	Joint Arrangement, not required under the Deed	Agreed at CEO meeting 6 August 2007	Completed but not signed
Public affairs management	Protocol required under Schedule 5 clause 3.1 of the Deed	Agreed at CEO meeting 7 December 2007 Revised 8 September 2008	Completed but not signed
Third party reviews	Protocol required under clause 16.2 of the Deed	Agreed at CEO meeting 11 February 2008 Revised 2 April 2008 Postponed/cancelled 14 August 2008 <a href="#">On hold as at March 2010 pending new Deed negotiations</a>	Not signed
Overseas supply	Joint arrangement, not Deed required	Draft sent to ARCBS 13 November 2008 <a href="#">March 2010, ARCBS have further revisions</a>	Signed 4 April 2008
Acknowledgement of Governments; funding	Agreement through consultation required under the Deed	Agreed at officer level 11 January 2008 Revised wording 3 March 2008 <a href="#">NBA requested compliance with protocol 19 August 2008</a>	Part of Public Affairs Joint Arrangement (see above)
Supply trend analysis	Joint arrangement required under clause 27.1 of the Deed	To be completed as part of Business Study recommendations and Output Based Funding Model development	Amendment required under Schedule 3 of the Deed
ARCBS activities other than under the Deed	Protocol required under clause 25.3 of the Deed	Not completed <a href="#">Partly replaced by the Output-based funding model in July 2010</a>	Partly completed
Quarterly CEO meetings	Joint Arrangement, not required under the Deed	Completed and agreed at CEO meeting 10 May 2007 <a href="#">To be revised as part of new Deed negotiations</a>	Completed but not signed
Notifiable events	Joint Arrangement, not required under the Deed	Joint arrangement not formally agreed, trialled throughout 2007–08 Review undertaken in July 2008	Signed 22 September 2009

Source: ANAO analysis from NBA files 26 March 2010 and NBA update December 2010.



## Appendix 6: Transfusion Medicine Services functions

The following table is compiled from the functions listed in the NBA-ARC Deed of Agreement and descriptions of those functions provided to the NBA by the ARCBS in June 2009. The table is provided for information, but may not reflect an up-to-date or government endorsed list, as the functions of the TMS have been under review since 2009.

Function	Description
<b>Leadership and engagement in relevant professional fora and advisory committees</b>	TMS is engaged in numerous activities to improve transfusion practice and outcomes at individual patient, hospital, and jurisdictional levels across the country. It contributes professionally to over 30 fora and Advisory Committees across all states and territories, and provides key membership for several national specialist and advisory committees involved in the development and implementation of guidelines to improve laboratory and clinical transfusion practice.
<b>Monitoring of trends in international clinical practice</b>	TMS provides four main functions through participation in several committees/projects, including: monitoring emerging diseases, epidemics and pandemics and developing disaster preparedness; new products scanning, assessment, integration and evaluation; desktop monitoring and review. TMS participates in around 12 international committees.
<b>Analysis of clinical basis for supply trends</b>	TMS provides a range of reports to NBA on supply trends including all fresh and plasma products, on an ad hoc, quarterly and annual basis. It also evaluates humanitarian requests for product support and provides technical support and coordination for monitoring the importation of rare blood for complex transfusion support.
<b>Oversight of agreements to supply, if any, with Approved Health Providers</b>	Up to 2008, the TMS participated in the NBA-ARCBS Agreement to Supply project which became the Re-engineering Our Supply and Services program.
<b>Development and delivery of information and education materials to Approved Health Providers</b>	TMS provides four functions in this area, including: support to jurisdictional based transfusion practice improvement initiatives; web-based educational material, pocket guides; convenes annual transfusion medicine courses; and convenes annual strategic blood forum.
<b>Promotion of and delivery in hospital transfusion committee and other transfusion quality improvement activities</b>	The TMS team promotes transfusion quality improvement through participation in over 60 hospital transfusion committees, and partakes in a range of audit, accreditation and peer review activities nationwide that are integral to improving clinical practice, patient management and transfusion laboratory practice, and reducing blood sector risks.
<b>Liaison with AHPs on appropriate inventory levels and inventory management practice including storage and handling of blood products</b>	TMS negotiates with AHPs on inventory levels and frequency of delivery, inventory management, storage and handling advice to AHPs, and liaises with laboratories external to ARCBS regarding inventory management and product handling practices. Between 2007 and 2009 TMS was involved in the development of a new model for red cell inventory and is working with all states and territories to develop appropriate inventory levels. Other national activities include auditing of laboratories.

<b>Collaboration with other bodies in the development and implementation of clinical practice guidelines</b>	<p>TMS provides expert input to around ten clinical practice guidelines projects, through collaboration and committee membership with several national societies, governments, standards bodies. TMS staff also coordinates working groups for key blood transfusion health issues (such as 'anti-D' antenatal prophylaxis) has contributed to guidelines and educational materials that have been adopted nationally (for example, the Bloodsafe e-learning package).</p>
<b>Management of Products in short supply including approvals for issue of Products, and monitoring and analysis of usage and expiry</b>	<p>TMS specifies six main functions against this requirement: National Blood Supply Contingency Planning activities; providing advice on intensive product management; policy, training and education for development of Emergency Donor Panel Support/policy; approval of access to IVIg and other products (there is some variation of this and the following two tasks across states/territories); maintains data on products in short supply; and collects blood discard data from 216 laboratories (about 5,300 records per month across all states/territories).</p>
<b>Transfusion medicine consultancy advice to individual clinicians</b>	<p>TMS medical officers provide advice on product use in general terms as it applied to specific patients.</p>
<b>Authorisation of products on a patient named basis</b>	<p>TMS medical officers authorise specific products on a named patient basis, for example HLA-and HPA-matched platelets. The TMS developed and manages the system which maintains records for ordering and approval of special requests.</p>
<b>Advice to clinicians in relation to adverse transfusion reactions and events</b>	<p>The TMS team is available through a 24/7 clinical on-call service, to advise clinicians about adverse reactions, product recalls and remedial action. Between 2006–08 TMS responded to 419 reports of adverse reactions (notifiable events within the Deed of Agreement). TMS also supports a range of haemovigilance programs and sentinel event reporting (daily monitoring of data) which assist in early intervention and reducing patient risk to transfusion reactions.</p>
<b>Delivery of undergraduate and postgraduate transfusion medicine training</b>	<p>TMS has been involved in the development of national practices, and with individual states/territories to the level and degree requested by the jurisdiction. Initiatives include: development of material for undergraduate and postgraduate transfusion medicine training; delivery of undergraduate, postgraduate, hospital tutorials; and in-service sessions in transfusion medicine training to over 67 universities, specialist colleges and hospitals.</p>
<b>Haemovigilance and blood safety systems and monitoring activities</b>	<p>TMS actively participates in haemovigilance activities. It is involved in the establishment and maintenance of haemovigilance and blood safety systems; development and monitoring activities under the NBA National Haemovigilance program; participates in the NBA Haemovigilance project working group; and complies with GMP reporting requirements.</p> <p>Diversity in the monitoring systems and level of TMS involvement was noted across the states/territories.</p>

Source: Compiled from the NBA–ARCS 2006–09 Deed of Agreement pp. 104–105, and the ARCBS detailed summary of provided to NBA and JBC in June 2009.

Note 1: TMS also undertakes research (a function not listed above but included in the Deed), for example: research into emerging and existing pathogens with the potential to affect blood; safety and efficiency of blood and products; and clinical transfusion medicine practice.

## Appendix 7: Case study—improving data availability

### Improving data availability through the development of ORBS and BloodNet

The ANAO examined the NBA's activities to improve data availability on the ordering and receipting verification of blood and blood products. It was necessary for the NBA to have access to such data to support the Output-Based Funding Model (OBFM).

**Development and implementation of a data system:** The Ordering and Receipting Blood System (ORBS), as the predecessor to BloodNet, was originally designed and implemented by Queensland Health to provide proof of receipt of blood products in Queensland. The NBA identified the value of the system to provide a national capability for the collection and use of data on the ordering and receipt verification of blood products, noting that it would: facilitate better supply planning from a demand perspective; increase traceability of blood and blood products; and improve record keeping.

**Progress:** In September 2009 the JBC agreed to fund a 'Proof of Concept Trial' over the period December 2009 to December 2010, to enable evaluation of governance and technical issues. This trial was reported a success by the NBA and JBC agreed in December 2010 to make BloodNet available nationally. Implementation of BloodNet is being undertaken in 2011. In May 2011, the NBA reported to JBC the status of implementation of BloodNet as:

- 'Implemented in all hospitals – Queensland, Tasmania[, South Australia and the Northern Territory];
- Pending implementation – Western Australia (likely late June) and Australian Capital Territory (date yet to be set); and
- Ongoing discussions – Victoria and New South Wales.'

The NBA advised that, to date, NBA expenditure for the development, implementation and maintenance of BloodNet (as a national system) is \$679,176, of a total approved budget of \$3.02 million.<sup>150</sup>

**Impact on the OBFM:** At the time of the audit, the NBA and ARCBS were negotiating a new Deed of Agreement with the ARCS/ARCBS for the supply of blood and blood services. An Output Based Funding Model was a key component under negotiation, as it would be used for calculating ARCBS funding.

Unless suitable information systems are in place for national data collection and management of the ordering, receipt and verification of blood and blood products, the NBA will not be well placed to:

- verify receipt of product for payment;
- forecast and plan supply;
- project ARCBS revenue budget; and
- monitor appropriate usage and wastage of blood products.

#### **Remaining vulnerability:**

As BloodNet (previously ORBS) was not implemented in all states and territories before the principles of the OBFM were finalised, and given the current lack of data on ordering practices, this is an area of high risk and blood sector vulnerability.

The detailed arrangements for the payment and substitution rules and national service standards to apply under the OBFM are also yet to be agreed. BloodNet will need to be updated to recognise these processes and associated rules.

Source: Compiled by the ANAO from NBA and JBC records, and NBA advice.

<sup>150</sup> Updated information provided by the NBA to the ANAO on 12 September 2011.

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